



Pharmacy HIV Testing Policies, Procedures and Quality Control

In Partnership with the Virginia Department of Health



January 2015

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This manual was supported by the Secretary's Minority AIDS Initiative Fund for Care and Prevention in the United States (CAPUS), grant number 1U62PS003949, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Table of Contents

Introduction.....	4
Policies and Procedures for Community HIV Testing.....	5
VDH Testing Requirements	6
Informed Consent	6
Client-Level Data Collection.....	6
Active Referral to Confirmatory Testing.....	7
Anonymous Testing	8
Policy for Mailing Confidential Patient Information	8
Record Storage and Retention Requirements.....	8
Ordering INSTI Rapid Test Kits and Forms.....	9
Relevant Law.....	9
Reporting Results	9
Related Laws	9
Quality Assurance Measures.....	10
Minimum Quality Expectations.....	10
Walgreens Testing Protocol.....	11
Quality Control Procedures.....	11
HIV Testing Process.....	14
Preparing Testing Area, Materials, and Equipment	14
Preparing to Conduct the HIV Test	15
Performing the HIV Test	16
Counseling on Results.....	20
Referrals for Confirmatory Testing	22

List of Attachments

Attachment A	Sample CTR Form.....	25
Attachment B	HIV Information and Testing Agreement.....	26
Attachment C	Pharmacist Referral to Confirmatory Testing.....	27
Attachment D	INSTI HIV-1 Antibody Test Kits and Controls Order Form.....	28
Attachment E	Order Form for CTR Forms and INSTI Related Supplies.....	29
Attachment F	INSTI Rapid HIV Test Problem Documentation.....	30
Attachment G	INSTI Rapid HIV Test Results Log.....	31
Attachment H	Pharmacist Testing Work Flow.....	32
Attachment I	Coordination of Confirmatory Testing Agreement Form.....	33
Attachment J	Referral Resources By Region.....	36
Attachment K	Sample Referral Card.....	40
Attachment L	VDH Policy Regarding Provision of Services to Minors.....	41
Attachment M	Regional Pediatric Testing Resources.....	43
Attachment N	Walgreens Store Site IDs.....	44
Attachment O	Walgreens HIV Testing Sites & Closest Local Health Departments.....	45
Attachment P	Health District Contact List.....	46
Attachment Q	Verification of Previous Diagnosis Form.....	51

Virginia Overview

Introduction

This document outlines policies, including standards, procedures, and quality assurance measures, for conducting Waived Rapid HIV Testing at Walgreens testing locations. This document also includes Quality Assurance (QA) activities for HIV testing sites authorized by the Virginia Department of Health (VDH), Division of Disease Prevention (DDP) to conduct Waived Rapid HIV Testing and Counseling.

Contained within are procedures for the INSTI HIV-1 Antibody Test Kit, which has been approved by the Food and Drug Administration (FDA), and granted a waiver by the Center for Medicare and Medicaid Services (CMS) in accordance with the Clinical Laboratory Improvement Amendments (CLIA) of 1988. The INSTI HIV-1 Antibody Test Kit is CLIA-waived only when used with the proprietary pipette and lancet provided by bioLytical Laboratories. In the absence of the proprietary pipette and lancet, the INSTI HIV-1 Antibody Test Kit is a moderately complex test.

QA guidelines contained in this document are specific to the retail pharmacy-based testing programs authorized by VDH, and focus primarily on Waived Rapid HIV Testing. QA refers to planned, ongoing, step-by-step activities designed to ensure that:

1. Testing is performed according to manufacturer guidelines.
2. Results are accurate and reliable.
3. Errors are found and corrected.

QA activities are conducted during the entire testing process; from the time test kits are received in the pharmacy to when they are used to perform HIV testing.

NOTICE: HIV testing is permitted only at locations identified by Walgreens Corporate and the Virginia Department of Health. Any personnel who engage in HIV testing outside of these sites are at risk for CLIA waived testing violations and therefore could be subject to discipline or termination.

Policies and Procedures for Community HIV Testing

Prior to conducting HIV rapid testing, pharmacists must complete the “HIV Testing and Counseling for Pharmacists” course offered by the Virginia HIV/AIDS Resource and Consultation Centers (VHARCC). This course has been specially developed to fulfill VDH requirements for training individuals to provide HIV testing, while minimally impacting the pharmacy workflow. The “HIV Testing and Counseling for Pharmacists” course consists of a half-day in-person training, which will be conducted at the pharmacist’s regional training facility, as well as prerequisite coursework, which has the following components:

Prior to attending the in-person training, pharmacists must complete the web-based CDC HIV testing course, “Rapid HIV Testing—Online,” which is available at <http://bit.ly/1mY2rjC>. Pharmacists must print their Certificate of Completion and present them to the VHARCC trainers at the in-person training as evidence of completion.

The pharmacists must review the pre-training reading materials provided by VDH. The pre-training reading will include overviews of Virginia reporting and partner notification law, the INSTI manufacturer’s booklet, outpatient treatment for HIV, and exercises to avoid emotional fatigue as a result of HIV testing.

The pharmacists must pass a pre-training knowledge check with a score of 70% or higher prior to attending the in-person training.

The Virginia HIV/AIDS Resource and Consultation Centers (VHARCC) are VDH’s primary resource for training pharmacists in HIV rapid testing and test counseling. No pharmacist will be considered qualified to begin providing HIV testing without first completing “HIV Testing and Counseling for Pharmacists”.

Training for new pharmacists should be arranged through the CAPUS Coordinator at 804-864-7945.

VDH Testing Requirements

Pharmacy locations offering testing will receive pre-filled Counseling, Testing, and Referral (CTR) forms, which must be used to report all HIV tests conducted by the pharmacists. The areas of the CTR form that have been pre-filled prior to arriving at the pharmacy should not be altered. Alteration of the pre-filled test forms may result in reporting errors that could hinder VDH's ability to document HIV tests performed by the pharmacists. This may delay the reimbursement process for the affected HIV tests. (See *Attachment A – Sample CTR Form*).

Sites providing HIV testing have been selected with respect to social determinants of health that are correlated with higher rates of HIV, including race and poverty. While HIV testing should be made available to everyone, VDH anticipates that these selection criteria will allow greater access to testing for Black and Latino adults. Pharmacists are encouraged to customize testing hours as needed to accommodate the needs of the targeted population groups. In the event it is needed, technical assistance is available by contacting the CAPUS Coordinator at (804) 864-7945 or Heather Bronson at (804) 864-8020.

Informed Consent

In order for a pharmacist to administer the test to a client, the client must first give consent. To give informed consent, the client must understand the purpose of the test, as well as the meaning of a non-reactive or a reactive result.

When that is completed, the pharmacist should give the client a few minutes to review the Manufacturers Subject Information Pamphlet and answer any questions. The pharmacist should then discuss the following things with the client:

- The difference between confidential and anonymous testing
- The difference between rapid and conventional testing
- The difference between a screening and confirmatory test
- The procedure for a negative result and a reactive result

The client should be asked if they have any questions or concerns before continuing. If not, the client should be asked about support systems in place if the test is reactive. Once the client has been adequately informed about the testing process, they can sign the consent form. See *Attachment B - HIV Information and Testing Agreement* for a sample VDH consent form.

While Virginia law does not require separate written consent for HIV testing, HIV testing sites conduct testing outside of clinical settings in which patients provide consent for medical care. It is recommended, therefore, that written consent be obtained to protect both the pharmacy and client whenever tests are performed in non-clinical settings. (See *Attachment B - HIV Information and Testing Agreement*).

Client-Level Data Collection

In order for an administered test to satisfy minimum contractual reporting requirements, it is necessary to collect the following required information:

- Year of birth
- State and city/county of residence

- Zip code
- Ethnicity
- Race
- Current Gender ID
- Assigned Sex at Birth
- Previous 900 Test?
- If so, what were the results?
- Test 1: Sample Date
- Test 1: Worker ID
- Test 1: Test Result
- Test 1: Result Provided
- Test 1: If results not provided, why?

If any of the above information is missing, the test cannot count toward CDC reporting requirements, and the HIV testing location will be asked by VDH to correct the test forms.

If the client does not identify with any of the given classes of race or ethnicity, the testing pharmacist should select “Declined” as their response.

If the client receives a preliminary reactive test result, the fields on the right side of the CTR form must also be completed:

- If positive result, referral?
 - Name of CBO/LHD
- Mode of Referral
- If Declined Referral, Why?

Once the client has left, it is important to ensure the completion of the CTR form, the test results log, and any other internal paperwork.

Prior to returning to the pharmacy, pharmacists should review the test form, verifying the accuracy of information recorded during the testing session and writing any useful additional information in the notes field at the bottom of the CTR form. The CTR Form ID number should be copied onto all interagency forms for proper tracking before separating the two copies of the CDC form.

Pharmacy test locations shall use the CTR Test Form and any other forms designated by VDH. The forms shall be completed accurately, completely and legibly, and submitted to VDH’s Central Registry Unit within 7 days of the test.

Active Referral to Confirmatory Testing

If a client receives a reactive result, the testing pharmacist should provide the client with an active referral to confirmatory testing. The pharmacist may choose to perform this active referral using the referral card listing local community partners, or the pharmacist may choose to contact Heather Bronson at (804) 397-5056 to have him/her facilitate the referral to a community partner. If the pharmacist chooses to provide an active referral to a community partner, he/she should contact the VDH representative following the referral to provide VDH with the name of the agency and staff person to whom the client has been referred. VDH will contact the referred agency directly to verify if the client is a new diagnosis, or if the client has previously been diagnosed and should be referred

directly to care. (See *Attachment C – Pharmacist Referral to Confirmatory Testing and Attachment J – Statewide List of Local Health Department Contacts*).

Anonymous Testing

Non-clinical testing supported by VDH is confidential, and not anonymous. This means that name and demographic information must be collected. (See *Attachment B - HIV Information and Testing Agreement*). Clients seeking only anonymous testing should be referred to the Virginia HIV/STD/Viral Hepatitis Hotline at 1-800-533-4148.

Policy for Mailing Confidential Patient Information

The original (white copy) of the CDC form is sent to VDH's Central Registry Unit at the following address. The carbon copy (yellow) should be retained by the pharmacy for internal recordkeeping:

Central Registry Unit
Virginia Department of Health
109 Governor Street, Room 228-E
Richmond, VA 23219

VDH's mailing policy for forms containing information related to HIV-testing requires two envelopes, an opaque inner envelope (such as a regular manila envelope), and a tear, puncture, and moisture-resistant outer envelope (such as a Tyvek envelope). VDH will provide all envelopes and mailing labels to testing pharmacies. CTR forms containing confidential patient information may be received via a secure mail system provided the mailing is done in a confidential manner that meets or exceeds the following guidelines:

- Forms should be placed inside the "first" or inner envelope and securely sealed with packaging tape. The number of forms placed within the envelope may not exceed 25 (or 1 inch stacked). The total number of forms being sent must be documented in the upper right corner on the outside of the inner envelope.
- The recipient and sender name and address shall be placed on the inner envelope. DDP will provide HIV testing sites with United Parcel Service (UPS) mailing labels for "return service." The UPS label must be placed on the "second" or outer envelope. Double addressing gives an additional level of security that the envelope will reach the intended person/address.
- The frequency of mailing will be on a weekly basis.

Record Storage and Retention Requirements

CTR documentation must be kept under VDH's three-lock rule—there must be three locks (example: locked Pharmacy door, locked office, locked cabinet) between the entrance of a pharmacy location and where patient identifying information is stored.

Pharmacies must retain CTR Form and other testing information containing patient identifiers for a period of five years, after which the pharmacy locations may destroy testing records. Custodians of records must ensure that information in confidential or privacy-protected records is protected from unauthorized disclosure through the ultimate destruction of the information. Ultimate destruction is

accomplished through cross-shredding, pulping, burning, and overwriting or physically destroying media. Deletion of confidential or privacy-protected information in computer files or other electronic storage media is not acceptable. Records containing Social Security numbers must be destroyed in compliance with 17VAC15-120-30; follow link for full code:

<http://lis.virginia.gov/cgi-bin/legp604.exe?000+reg+17VAC15-120-30>. Pharmacies should use the Blank RM-3 Form located at <http://www.lva.virginia.gov/agencies/records/forms.asp> to document record disposal.

If a pharmacy ceases operations prior to the end of the five-year period, or if VDH deems that confidentiality is not being maintained, all CTR forms and other testing information containing patient identifiers must be returned to VDH for storage.

Ordering INSTI Rapid Test Kits and Forms

INSTI test kits and CTR forms and supplies can be ordered by completing and faxing their respective order forms (see *Attachment D – INSTI HIV-1 Antibody Test Kits and Controls Order Form* for and *Attachment E – Order Form for CTR Forms and INSTI Related Supplies*) to the CAPUS Coordinator at 804-864-7970. Test kit and controls also can be ordered on StoreNet at: SNet>Patient Care>Health Testing>HIV Testing>Forms/Equipment>Testing Site Order Form.

As the length of time required to ship forms may vary, it is recommended to keep at least 200 CTR forms on-hand.

As the length of time required to ship INSTI tests internationally is significant, it is recommended to keep at least a one-month supply of test kits on-hand (the exact number will vary by individual store). Should you run low or run out of tests please contact your supervisor immediately.

Any questions regarding ordering of forms or test kits can be addressed to the CAPUS Coordinator by phone.

Relevant Law

Reporting Results

All information collected from clients, including test results, is used for epidemiological data and is reported to VDH in accordance with the Code of Virginia. In the event of a confirmed reactive result, a new surveillance case will be opened, and a DIS will be sent to interview the client and offer them assistance in notifying their sexual and/or drug use partners that they may have been exposed to HIV. The DIS will also offer HIV testing to any partners identified by the client.

Related Laws

HIV/HBV Infected Healthcare Workers and Occupational Exposure. *Year 1993 SB 829 §32.1-45.1*. Deemed consent to testing and release of test results related to infection with human immunodeficiency virus or hepatitis B or C viruses. <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+32.1-45.1+501054>

AND

HIV Testing *Year 1995 HB 1921 § 54.1-2403.01*. Routine component of prenatal care. <http://leg1.state.va.us/cgi-bin/legp504.exe?000+coh+54.1-2403.01+702271>

AND

Year 2008 § 32.1-37.2 Section A Consent for testing for human immunodeficiency virus; condition on disclosure of test results; counseling required; exceptions.

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-37.2>

Quality Assurance Measures

Minimum Quality Expectations

1. Clients must be tested in a confidential manner, and in a location that provides privacy.
2. Testing pharmacists must complete all mandated trainings before conducting rapid HIV testing. See page 4 for details.
3. Testing pharmacists conducting rapid HIV testing shall determine, on an individual basis, the sobriety and/or mental status of each client. A rapid HIV test shall not be performed, nor results provided, if the tester believes that the client cannot comprehend the meaning of the test or may be a danger to him or herself or others.
4. Persons who have identified themselves as HIV-positive and who are requesting a test to prove their status for any reason, such as medical care, case management, etc., shall not be retested with a rapid HIV test. Instead, these individuals shall be referred to the local health department or an infectious disease clinic for serum testing. In some cases, HIV-positive individuals may present for testing in order to maintain their own confidentiality (i.e., large-scale testing events, a group of friends who all decide to get tested together, etc.). In these cases, a rapid test can be performed, but a confirmatory test need not be conducted. For continuity of paperwork, pharmacies shall collect sufficient data needed to confirm a client's previous HIV diagnosis, and transmit this information to VDH (*See Attachment Q – Verification of Previous Diagnosis Form*).
5. Testing pharmacists may provide testing only to those clients who sign the HIV Information and Testing Agreement (*See Attachment B - HIV Information and Testing Agreement*) or another VDH-approved consent form.
6. Before conducting an HIV test, testing pharmacists shall inform the client that the test is a screening test, and further testing must be done to confirm a preliminary positive result. In delivering a preliminary positive HIV test to a client, pharmacists shall again remind the client that the test is a screening test and that a confirmatory test will need to be conducted by a partner agency.
7. All testing sites must display a copy of the original CLIA certificate of waiver.
8. Pharmacists shall offer the client the INSTI HIV-1 Antibody Test Subject Information Brochure during the testing session.
9. Pharmacists conducting testing shall read and understand the package insert. Pharmacists also must have read the **Pharmacy HIV Testing Policies, Procedures and Quality Control** document (this manual), which is accessible on StoreNet.

Walgreens Testing Protocol

Quality Control Procedures

INSTI HIV-1 Antibody Test Kit External Controls

When to Run Controls

- **INSTI HIV-1 Positive and Negative Controls must be run under the following circumstances:**
 - With each newly-trained INSTI operator prior to performing their first test on patient specimens
 - When opening a new INSTI test kit lot
 - Whenever a new shipment of test kits is received (even if test kits are from the same lot previously received)
 - If the temperature of the test kit storage area falls outside of 59-86°F
 - If the temperature of the testing area falls outside of 59-86°F

Quality Control Specimen Handling

- Test Kit Controls will be placed in the freezer immediately upon receipt of shipment.
- Test Kit Controls are to be stored at a temperature of $\leq -4^{\circ}\text{F}$ when not in use for up to 1 year. Remove from storage at $\leq -4^{\circ}\text{F}$ and allow the Controls to reach room temperature before testing with INSTI. Test Kit Controls should be left out for 15 minutes in order to come to room temperature.
- Once the controls are thawed following storage at $\leq -4^{\circ}\text{F}$, they remain stable for 28 days in the refrigerator at a temperature of 35.6-46.4°F. Do not re-freeze. When control vials are opened, they will be marked with the date opened and the date to be discarded (28 days from open date). Each Control vial contains enough specimen to conduct 8 quality control tests.
- Temperature of the freezer and refrigerator will be monitored by the pharmacy staff twice daily and will be documented on the Temperature Log.
- Do not use Test Kit Controls beyond the expiration date.

Performing External Controls

- Cover the workspace area with a clean, absorbent underpad.
- The testing pharmacist is to put on gloves prior to starting the Quality Control process.
- Remove one Positive Control vial and one Negative Control vial from storage at $\leq -4^{\circ}\text{F}$ and allow Controls to reach room temperature before testing with INSTI. Test Kit Controls should be left out for 15 minutes in order to come to room temperature.
- Open the INSTI HIV-1 Test Membrane Unit by tearing at the notches on the top of each side of the foil pouch. Do not touch the center well of the Membrane Unit. Do not use if the foil pouch has been previously opened or if the packaging integrity is compromised in any manner. Once the Membrane Unit has been opened, it must be used immediately.
- Place the Positive Control vial and Membrane Unit on the absorbent pad with the tab of the Membrane Unit facing the testing pharmacist.
- Remove one vial of Sample Diluent (Solution 1), Color Developer (Solution 2), and Clarifying Solution (Solution 3) and place on absorbent pad. Remove one single-use pipette and place on absorbent pad.

- Mix the Positive Control by swirling for 5 seconds prior to use. Uncap the Positive Control vial. Take the pipette and lightly depress the top bulb. Insert the pipette tip into the clear liquid in the Positive Control vial, slowly releasing the top bulb to completely fill the pipette stem. Ensure that the liquid in the stem reaches only to the fill line, designating 50 µL. Open the Sample Diluent (Solution 1) and transfer the Positive Control sample held in the pipette to the Sample Diluent bottle by completely squeezing the pipette bulb. Recap the Sample Diluent bottle and mix by inversion for 5 seconds.
- Pour the entire contents of the Sample Diluent bottle to the center of the Membrane Unit well.
 - This must be done within 5 minutes of adding the Positive Control specimen to the Sample Diluent. The mixture should be absorbed through the membrane in less than 30 seconds; however, absorption times will vary slightly.
 - **IMPORTANT:** If at any period during the quality control procedure, the Sample Diluent, Color Developer, or Clarifying Solution stop flowing through the Membrane Unit, the procedure must be stopped and re-started with new INSTI components.
- Re-suspend the Color Developer (Solution 2) by inversion for 5 seconds. Open the Color Developer and add the entire contents to the center of the Membrane Unit well. The colored solution should flow through completely in about 20 seconds.
- Open the Clarifying Solution (Solution 3) and add the entire contents to the center of the Membrane Unit well. This will reduce the background color and facilitate reading of the test result. Immediately read the result once the solution is through the well.
 - **Do not read the results if more than 5 minutes have elapsed following addition of Clarifying Solution.**
- The HIV-1 positive quality control test result should read Reactive. The test is Reactive if both the control spot and the test spot show blue color development. One spot may be darker than the other.
- The HIV-1 negative quality control test results should read Non-Reactive. A test is Non-reactive if only the control spot shows blue color development. No blue spot should be visible at the test spot, located below the control.
- The test is invalid if any of the following occurs:
 - There is no blue color on the control or the test spot
 - There is blue color on the test spot, but not the control spot
 - There is a uniform tint across the membrane
 - Only blue specks appear on the membrane
- If the negative or positive controls do not provide the expected results, notify the Pharmacy Lab Director of the situation. The testing staff will review the process for conducting the control with a new control kit to rule out cross contamination or operator error.
- If corrective action does not resolve the problem, testing with the control kits will cease, **patients will not be tested** with supplies in the affected testing kit, and the testing pharmacist will contact the Manufacturer at 1-866-674-6784 (bioLytical) to report the problem. (See *Attachment F – INSTI Rapid HIV Test Problem Documentation*).
- The Pharmacy Manager is to report any quality control issues via the Health Testing Technical Issues Web form located on StoreNet: SNet>Patient Care>Health Testing>Technical Issues
 - In addition to reporting quality control issues internally and to the Manufacturer, persistent issues should be reported to the CAPUS Coordinator at 804-864-7945 for technical assistance.
- Record the results and corrective actions on the INSTI Rapid HIV Test Problem Documentation (see *Attachment F – INSTI Rapid HIV Test Problem Documentation*).
- Dispose of the used Membrane Unit, Solution vials, and pipette in the biohazard waste container. All other materials may be disposed of in the trash.

- Repeat the above procedures for the HIV-1 Negative Control using a new INSTI Membrane Unit, Sample Diluent, Color Developer, Clarifying Solution, and pipette.
- Each Control vial contains enough specimen to conduct 8 quality control tests. Upon completion of the quality control tests, the Positive and Negative Control vials must be placed in the refrigerator at a temperature of 35.6-46.4°F where they remain stable for 28 days. Do not re-freeze. Once control vials are opened, they will be marked with the date opened and the date to be discarded (28 days from open date).

The test kit controls shall give the expected reactive or non-reactive result or the test results are not valid. If test kit controls do not provide expected results after being repeated, contact the CAPUS Coordinator (804) 864-7945 or Heather Bronson (804) 864-8020.

HIV Testing Process

Preparing Testing Area, Materials, and Equipment

Testing Supplies

Item	Source
Counseling, Testing and Referral (CTR) Form – Part 1 ★	VDH
INSTI HIV-1 Antibody Test Kits	bioLytical (orders must be placed 4 weeks in advance)
INSTI HIV-1 Antibody Test Kit Controls	bioLytical (orders must be placed 4 weeks in advance)
Alcohol Prep Pads	bioLytical (orders must be placed 4 weeks in advance)
Band-Aids	Walgreens
Disinfecting wipes	Walgreens
Underpads	VDH
Clipboard	VDH
Gauze Sponges 2" x 2"	Walgreens
Gloves	Walgreens
Hand Sanitizer	Walgreens
Lancets (included with test kits)	bioLytical
Sample collection Pipette	bioLytical
Sharps Containers	VDH

★ As the time required to ship forms may vary, it is recommended to keep at least 200 CTR forms on-hand.

For the Virginia Department of Health project, the INSTI HIV-1 Antibody Test Kit and Controls will be ordered by completing and faxing the INSTI Test Kit and Controls order form (see *Attachment D - INSTI HIV-1 Antibody Test Kits and Controls Order Form*).

- The Pharmacy Manager will order the Test Kits and Test Kit Controls by completing and faxing the Supply Order Form to the CAPUS Coordinator at 804-864-7970. The form can be located on StoreNet at: SNet>Patient Care>Health Testing>HIV Testing>Forms/Equipment>Testing Site Order Form.
- Underpads, clipboards, and sharps containers will be ordered by completing the *Order Form for CTR Forms and INSTI Related Supplies (Attachment E)*.
- Complete the form with the following information.
 - Pharmacy Address
 - Date
 - Site representative/Contact Name
 - Pharmacy phone number/Contact Phone Number
 - Quantity of Item Needed
 - Indicate if Urgent (Yes/No)
 - Comments or notes regarding request
- Once the form is completed, fax the order request to the CAPUS Coordinator at 804-864-7970
- All other supplies will be ordered through Walgreens..
- Upon arrival of the Test Kit and Test Kit Controls to the pharmacy, the pharmacist is to review the Customer Letter (package insert) to identify any procedural updates or changes. The Customer Letter is to be kept on file with the test kit and control package insert in the CLIA Waived Health Testing Binder.
- The test kit Customer Letter and control package inserts should be discarded when a new test kit or control solution is delivered to the pharmacy. The pharmacy is to only retain the most current copy of the manufacturer's instructions for the test kit and controls.

Testing Area

- The testing area for the INSTI HIV-1 Antibody Test must meet the following minimum requirements:
 - Room temperature within the operating range of the test (59-86°F).
 - Contain a stable work surface that can be covered with an absorbent underpad.
 - Contain adequate seating for the client and pharmacist.
 - Within reach of appropriate materials, including one sealed test pouch containing INSTI Membrane Unit, one vial of Sample Diluent, Color Developer, and Clarifying Solution, alcohol prep pad, lancet, and pipette
 - Adequately lit to allow interpretation of the test result. As a rule of thumb, lighting is sufficient if standard newsprint held next to the text device can be read without difficulty. A mini flashlight can also be used to help read the testing device.

Preparing to Conduct the HIV Test

Patient Identification and Preparation

- HIV tests are available to adults 18 years of age and older.
- Any patient that is requesting an HIV Test as the result of sexual assault or worksite related needle-stick event are to be referred to the nearest emergency room for appropriate emergency care.
- After patient identification, it is required that the testing pharmacist take all documents and testing materials to the private consultation area. Patient privacy is essential for all steps of HIV education and testing.
- **IT IS REQUIRED** that prior to testing the patient receive and read the **INSTI HIV-1 Antibody Test -- Subject Information Brochure** titled "What You Should Know About HIV and the INSTI HIV-1 Antibody Test Before Testing."
- Address any questions the patient may have about the test or the information contained in the pamphlet.

Pre-Test Education and Documents to be Completed:

- Patient education is critical when providing rapid HIV testing. All HIV testing sites will adhere to the following guidelines:
 - The patient will be given information and counseling about the HIV test, its purpose, potential uses, limitations and the meaning of its results, and about ways HIV is transmitted and how it can be prevented. Patients will also be counseled about the testing procedures to be followed, that the HIV test is voluntary, the right to withdraw from the testing before completion of the test, the availability of referral to anonymous testing (if desired), and the right to confidential treatment of the test and test results, to the extent provided by applicable law.
 - Manufacturers of rapid HIV tests, including INSTI HIV-1 Antibody Test, provide a subject information brochure that **must be given** to each patient prior to performing the test, in accordance with FDA sales restrictions.
 - The patient is to be advised that their rapid test results will be made available to them during the same visit. The pharmacist will ask the patient if they are ready to receive test results within 1-3 minutes of starting the test. If the patient does not think they can receive test results on the same day the test is done, the pharmacy should recommend that the patient seek out traditional HIV testing.

- To provide the appropriate level of information for a potential HIV testing patient, the pharmacist should use the one page process flow document titled: **Pharmacist Testing Work Flow** (see *Attachment H*).
- Patients being tested at a Walgreens Pharmacy location must provide informed consent by completing the Walgreens HIV Information and Testing Agreement.
- The testing pharmacist must complete the Virginia Department of Health CTR Form. Prior to testing, the pharmacist should obtain the following patient information:
 - Printed name (on consent form)
 - Year of birth
 - State
 - Zip code
 - Ethnicity
 - Race
 - Gender assigned at birth
 - Current gender
 - Previous 900 Test through Virginia Department of Health
 - Self-reported result from previous 900 Test

Set Up and Preparation

- Do not use the INSTI Membrane Unit or Solutions beyond the expiration date.
- Test development procedures are to be conducted in the private consultation area of the pharmacy.
- Cover the workspace area with a clean, absorbent pad.
- The testing pharmacist is to put on gloves prior to starting the testing process.
- Describe for the patient the collection procedure.
- After the patient confirms understanding of the test, open the INSTI HIV-1 Test Membrane Unit by tearing at the notches on the top of each side of the foil pouch. Do not touch the center well of the Membrane Unit. Do not use if the foil pouch has been previously opened or if the packaging integrity is compromised in any manner. Once the Membrane Unit has been opened, it must be used immediately.
- Place the Membrane Unit on the absorbent pad with the tab of the Membrane Unit facing the testing pharmacist.
- Remove one bottle of Sample Diluent (Solution 1), Color Developer (Solution 2), and Clarifying Solution (Solution 3) and place on absorbent pad. Remove one single-use precision pipette, lancet, and alcohol swab and place on absorbent pad.

Performing the HIV Test

Specimen Collection and Handling

- Walgreens pharmacists will only use Fingerstick Whole Blood Samples when conducting rapid HIV tests.
- Choose a spot on the side of one of the center fingers (3rd or 4th finger) of the non-dominant hand. To help increase blood flow, the fingers and hand should be warm to the touch. Patients can rub their hands together, run under warm water in the restroom, or squeeze them together to increase blood flow to the capillaries in the fingertips.
- Clean the site with an alcohol swab. Wipe well to remove any glycerin based soaps or lotions from the patient's finger. Allow the site to dry completely to prevent additional pain.
- Use of the **21 gauge** single-use lancet provided with INSTI test is necessary to collect the 50 µL of blood need to conduct the test. Twist and pull the green tip out of the single-use lancet. Place the

lancet at the desired site and press firmly until you hear a click to puncture the skin. **It is against Company policy to use the lancets or lancing devices that are not single-use safety inserts to perform patient testing (i.e., blood glucose monitor lancets).** This type of lancet and lancing device is intended ONLY for a single patient for at home use.

- Discard the lancet into the biohazard waste container immediately after use.
- Squeeze the finger gently to create a drop of blood. Wipe away the first drop of blood, as it may contain tissue fluid.
- Squeeze the finger gently again while holding it downward until a large drop of blood forms. Apply pressure proximal to the site using thumb and forefinger of non-dominant hand to keep a bead of blood forming.
- Place the pipette tip horizontally into the blood bead. The pipette tip must be completely submerged in blood for the capillary action to work and draw the blood to the black fill line. Do not squeeze the pipette bulb or cover the air hole between the black lines.
- Fill the pipette to the black line to obtain 50 µL of blood.
- If an air bubble develops on the end of the pipette tip or if the blood stops moving up the pipette, gently wipe the tip of the pipette with a gauze pad. Wipe the patient's finger with a gauze pad and squeeze the finger until a large drop of blood forms again.
- If the volume of blood is inadequate, perform a second finger puncture using a new lancet and pipette.
- Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops and then bandage the patient's finger.

Running the Test

- Once the pipette is filled to the black line, the blood specimen will be transferred to the Sample Diluent.
- Open the Sample Diluent (Solution 1) and align the tip of the pipette with the Sample Diluent. Squeeze the bulb of the pipette to transfer the blood specimen to the Sample Diluent. If the blood specimen does not release, cover the air hole on the black line with your fingers and squeeze again.
- Recap the Sample Diluent bottle and mix by inversion for 5 seconds.
- Pour the entire contents of the Sample Diluent bottle to the center of the Membrane Unit well.
 - This must be done within 5 minutes of adding the Positive Control specimen to the Sample Diluent. The mixture should be absorbed through the membrane in less than 30 seconds; however, absorption times will vary slightly. Allow the solution to be absorbed completely, then immediately proceed to the next step.
 - **IMPORTANT:** If at any period during the testing, the Sample Diluent, Color Developer, or Clarifying Solution stop flowing through the Membrane Unit, the procedure must be stopped and re-started with new INSTI components. The pharmacist should record the lot number of the test kit, and contact the CAPUS Coordinator at 804-864-7945., who will convey that information to the test manufacturer. If two kits within the same box present this abnormality, testing shall cease and a VDH will obtain a new lot of test kits for the pharmacy.
- Re-suspend the Color Developer (Solution 2) by inversion for 5 seconds. Open the Color Developer and add the entire contents to the center of the Membrane Unit well. The colored solution should flow through completely in about 20 seconds. Allow the solution to be absorbed completely, then immediately proceed to the next step.

- Open the Clarifying Solution (Solution 3) and add the entire contents to the center of the Membrane Unit well. This will reduce the background color and facilitate reading of the test result. Immediately read the result once the solution is through the well.
 - **DO NOT read the results if more than 5 minutes have elapsed following addition of Clarifying Solution.**

Test Result Interpretation

- Read the results immediately after absorption of the Clarifying Solution.
- **DO NOT** read the results if more than 5 minutes have elapsed following addition of the Clarifying Solution.

	NON-REACTIVE	REACTIVE	INVALID
Appearance of Result	The control spot at the top of the read frame furthest from the plastic tab on the Membrane unit shows blue color development <u>AND NO</u> blue spot is visible at the test spot, located below the control.	The control spot <u>AND</u> the test spot show blue color development. NOTE: One spot may be darker than the other.	The test is invalid if any of the following occurs: <ul style="list-style-type: none"> • There is no blue color on the control spot or test spot • There is blue color on the test spot, but not the control spot • There is a uniform tint across the membrane • Only blue specks appear on the membrane
HIV Antibodies	A Non-Reactive test results means that HIV-1 antibodies were not detected in the specimen.	A Reactive test result means that HIV-1 <u>has been detected</u> in the specimen.	
Interpretation	Negative for HIV-1.	PRELIMINARY POSITIVE for HIV-1 antibodies.	An Invalid test result cannot be interpreted. The test was run incorrectly or insufficient specimen was added. Repeat the test with a new specimen, Membrane unit, kit components, and supporting materials. Contact bioLytical Laboratories' Technical Support if the repeat test provides an Invalid Test Result. Document on Walgreens

	NON-REACTIVE	REACTIVE	INVALID
			Health Testing Technical Issues Web Form
Counseling (See After Testing-Counseling on Results)	<p>Explain the meaning of the test result in simple terms, avoiding technical jargon.</p> <p>Convey that they are not infected with HIV, unless they have had a recent—within three (3) months—known or possible exposure to HIV.</p>	<p>Explain the meaning of the screening test result simple terms.</p> <p>Emphasize the need for confirmatory testing for a reactive (preliminary positive result).</p>	Explain to the patient that the test must be repeated. It will be necessary to collect a new specimen and run a new test
Referral	If a patient falls within the three (3) month “window” period, recommend retesting. Explain that sufficient time needs to elapse before antibodies develop that can be detected by the test. Recommend retest in 3 months.	Provide patient with information to assist with confirmatory testing and linkage to care.	Refer patient to traditional HIV Testing sources if second test is invalid or patient refuses second test.

- The testing pharmacist is to immediately transcribe the patient results on the:
 - **Virginia Department of Health CTR Form**
 - **INSTI Rapid Test Results Log** (see *Attachment G – INSTI Rapid HIV Test Results Log*)
- To maintain patient privacy, record these results in the pharmacy out of the view of customers, other clients or other providers after testing has been conducted.
- All patient identifiable records are to be filed in a locked file cabinet in the pharmacy.

Test Limitations

- Although the membrane contains HIV-1 and HIV-2 proteins, the assay has been validated for detection of HIV-1 antibodies only.
- For a Reactive result, the intensity of the test spot does not necessarily correlate to the titer of antibody in the specimen.
- Reading test results after more than 5 minutes has elapsed following addition of Clarifying Solution may yield erroneous results.
- Patients infected with HIV-1 or HIV-2 receiving Antiretroviral Therapy may produce false negative results.
- Specimens from patients with multiple myeloma may result in false Non-Reactive or Invalid results.
- Patients with elevated hemoglobin levels may test false Non-Reactive.
- A Non-Reactive Result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.

- A person who has antibodies to HIV-1 is presumed to be infected with the virus, except if that person has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.

Counseling on Results

Confidentiality

- Ensuring confidentiality of the patient is a critical part of providing HIV Testing Services. All patient information is confidential, whether the patient is tested or decides to decline rapid HIV testing.
- **Test results will be shared only with the patient and cannot be shared with others,** with the exception of required disclosure to the Virginia Department of Health. In the event that a patient requests to have their test result shared, they must provide a signed Authorization of Release of Information, which names the specific party to whom disclosure is permitted, **prior to** information disbursement. Walgreens Privacy Office consultation is required for all other disclosures without written patient approval.
- Releasing of test results or any information leading to disclosure of the identity of a patient without the written consent of the patient is a breach of confidentiality and punishable by applicable State statutes and administrative regulations.
- Pre-test and post-test education must be performed in a private area or room with a closed door, where no one can see the specimen collection and testing being done or hear the conversation. (Counseling must always be done one-on-one to determine informed consent.)
- Files and logs with identifying patient information will be kept in a locked cabinet in the pharmacy. These files are only accessible to the testing pharmacists.

Post-test Education: Communicating the Meaning of Rapid HIV Test Results to Patients

- The pharmacist that conducts the testing will be responsible for communicating the results of the rapid HIV test to the patient. It is important to keep in mind that the rapid HIV test is a screening test, and the patient who tests preliminary positive need to have their test results validated with a confirmatory test.
- Guidelines follow for conveying test results to patients receiving HIV testing.
 - **Negative (Nonreactive) Rapid HIV Test Result**
 - For patients with a negative (nonreactive) test result, it is essential to:
 - Explain the meaning of the test result in simple terms, avoiding technical jargon.
 - Convey that they are not infected with HIV, unless they have had a recent—within three (3) months—known or possible exposure to HIV.
 - If a patient falls within the three (3) month “window” period, recommend retesting. Explain that sufficient time needs to elapse before antibodies develop that can be detected by the test. Underscore the importance of taking precautions to avoid becoming infected with HIV. Provide patient with the written patient education piece titled HIV Risk Reduction Patient Education.
 - All patients that receive rapid HIV testing are to receive the (city/state specific) patient education piece titled Risk Reduction Patient Education. This

patient education piece also contains local referral sources for HIV counseling.

○ **Preliminary Positive (Reactive) Rapid HIV Test Result**

- For patients with a preliminary positive (reactive) test result, it is essential to:
 - Provide reactive result to this screening test clearly and simply.
 - Explain the meaning of the screening test result in simple terms.
 - Emphasize the need for confirmatory testing.
 - Assess how the patient is coping with the result.
 - Advise the patient to take precautions to avoid transmitting infection to others while awaiting results of confirmatory testing.
 - Further testing is always required to confirm a preliminary positive (reactive) test result. Testing pharmacists need to keep in mind that providing preliminary positive results to patients without the benefit of a same-day confirmatory test can be a challenge. For all patients with a preliminary positive test result, it is essential to:
 - Explain the meaning of the test result in simple terms, avoiding technical jargon. Use language to convey the probability that the patient is infected with HIV, e.g., infection is “possible, likely, or probable.”
 - Emphasize the importance of confirmatory testing and provide a referral for confirmatory testing. Provide referrals to the patient, as appropriate, if they are experiencing anxiety and stress related to having to get a confirmatory test.
 - Underscore the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of confirmatory testing. Provide patient with written information about risk reduction.
 - A simple, straightforward message to convey this information could be “Your preliminary test result is positive, but you won’t know for sure if you are infected with HIV until you get the results from your confirmatory test. In the meantime, you should take precautions to avoid transmitting the virus.”
 - All patients that receive rapid HIV testing are to receive the (city/state specific) patient education piece titled Rapid HIV Testing Patient Education. This patient education piece also contains local referral sources for HIV counseling.

○ **Invalid (Indeterminate) Rapid HIV Test Result**

- While an invalid test result occurs rarely, it is a possibility. If a patient has an invalid test result, it is essential to:
 - Explain to the patient that the test must be repeated. It will be necessary to collect a new specimen and run a new test.
 - Explain to the patient the reasons why the test could not be interpreted. Invalid tests occur because the test was run incorrectly or insufficient specimen was added.
 - Assure the patient that quality control measures are in place in order to accurately conduct the test.

- Be sure the patient understands that an invalid test is not a positive or a negative result. Something happened to render the test invalid and this is unrelated to the patient's HIV status.
- If the patient does not have the time for another test, they will be scheduled to return on another day.

Referrals for Confirmatory Testing

- Pharmacists involved with this service are responsible for the coordination of confirmatory testing for any patient who receives a preliminary reactive test result. (See *Attachment C– Pharmacist Referral to Confirmatory Testing*). Pharmacists will use the Coordination of Confirmatory Testing Agreement (CCTA) form (see *Attachment I*) to refer clients to testing with a partner agency.
- After providing the appropriate post-test counseling to the client, the pharmacist should decide whether he/she will provide a direct referral to the client, or have VDH facilitate a referral.
- If the pharmacist prefers to provide a direct referral to the client, he/she should:
 - Select an agency from the front of the Confirmatory Testing Referral Card (CTRC). Priority should be given to DIS in the county where the client resides (see DIS contacts in *Attachment P – Health District Contact List* and a sample referral card in *Attachment K - Sample Referral Card*).
 - Contact the agency with the client using the provided contact information and coordinate a time for the client to receive confirmatory testing at the agency office.
 - Write the appropriate time and date of the client's appointment on the CTRC.
- If the pharmacist prefers to have VDH facilitate a referral, he/she should:
 - Contact the VDH representative at 804-397-5056.
 - VDH will speak with the client to determine their referral preference.
 - VDH will call the agency representative, then merge both calls so that the client and agency can speak directly to each other
 - Write the appropriate time and date for the client's appointment on the CTRC.
- Any time that there is a preliminary positive client, the pharmacist should contact the appropriate VDH representative and provide the name of the agency and agency staff-person who spoke with the client, so that VDH can track the case.
- In addition to referrals to confirmatory testing, pharmacists may also provide referrals to other resources using VDH's HIV/STD/Viral Hepatitis Hotline. The number for the Hotline is listed on the Confirmatory Testing Referral Card, and pharmacists may provide this card to people with negative results who indicate a need for non-testing social services.

Patient Failure to Return for Test Results

It is possible that the patient being tested is not prepared to receive their test results. In the event that patient leaves the pharmacy before receiving their results the follow procedures are to be followed.

Upon Patient Return to the Pharmacy:

- If the patient returns to the pharmacy to receive their results, the pharmacist will confirm the patient's identify with a photo ID.
- After photo ID verification, a HIV testing trained pharmacist will locate the patient's HIV Information and Testing Agreement form.
- Any pharmacist trained on HIV testing can provide the information to the patient, the pharmacist that conducted the test is not required to be the pharmacist to share the information.

- The HIV testing trained pharmacist will provide the patient's results in the private consultation area and complete post-testing procedures, as described in the procedures provided previously.

Contacting Patients to Return for Results

- Walgreens HIV testing trained pharmacists are required to make a good faith effort to inform the patient of their HIV test results. This is the case no matter what the result is (non-reactive, reactive, or invalid).
- If the patient fails to return within 3 days of being tested, the pharmacist will be permitted to contact the patient via phone to encourage their return to the pharmacy for the result.
- All patients must return to the pharmacy for their results to be delivered **to them in person at the pharmacy**, after photo ID validation. **It is strictly forbidden to release any patient HIV testing information over the phone.**
- If the patient does not provide a phone number, then the pharmacist will send a certified letter using the procedures listed below.
- Phone calls are to be generic in nature and are not to provide any information around the nature of the service provided or the results obtained
"Hello Mr. Jones, this is the pharmacist at Walgreens. I am requesting that you return to our pharmacy for some information."
- Should the patient call the pharmacy back to request information over the phone, the pharmacist is to apologize; however, we cannot release confidential information over the phone. The patient is to be informed that they must come to the pharmacy to receive this information in person.
- The date and time the call performed is to be documented on the HIV Information and Testing Agreement form.

Final Request to Return for Results:

- If the patient fails to return within 7 days after being contacted via phone, the pharmacist will send a certified letter to the patient to encourage their return to the pharmacy for the test result.
- The letter is generic in nature and does not provide any information on the nature of the service provided or the test result obtained.
- A template letter is provided on StoreNet at: SNet>Patient Care>Health Testing>HIV Testing>Equipment/Forms>Return to Pharmacy Letter
- The letter is to be sent via certified mail with signature confirmation.
- A copy of the letter and the signature confirmation are to be stapled to the HIV Information and Testing Agreement form and kept on file in the pharmacy in the locked file cabinet.

Testing Reporting

- Participating locations will be required to mail completed CTR Form and Coordination of Confirmatory Testing Agreement Forms (CCTA) to the Department of Health each month.
- The pharmacy team is to make a copy of all CCTA forms that are being sent to the Virginia Department of Health.
- Refer to the VDH Secure Mailing Policy listed on page 7 of this manual for step-by-step instructions.

Biohazard and Waste Disposal

- Dispose of the lancet device, membrane unit, solution vials, and expired control solutions, into the biohazard container.
- The absorbent pad and gloves can be discarded in the regular trash.
- Upon their expiration, test kits can be discarded in the regular trash.

- After disposing of gloves and the testing pharmacist is to wash his/her hands.
- Disassemble testing area and clean with VDH-provided disinfecting wipes. Allow 60 minutes for effective decontamination.


Device Care

- The HIV Testing supplies do not have return privileges and should be discarded by the following procedures:
 - Expired rapid HIV test kits are to be discarded in the regular trash.
 - Expired control solutions are to be discarded into a sharps container.

Attachments

Attachment A

Sample CTR Form

CTR (900) FORM PART 1				
Imprint Barcode (Form ID) Here		Date Modified: 08/15/14		
PROGRAM ANNOUNCEMENT NUMBER				
<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> PS12-1201-Category A <input type="checkbox"/> PS12-1201-Category B </div> <div> <input type="checkbox"/> PS12-1201-Category C <input type="checkbox"/> PS08-803 </div> <div> <input type="checkbox"/> PS10-1003 <input type="checkbox"/> PS11-1113 </div> <div> <input type="checkbox"/> MSM Testing Initiative <input checked="" type="checkbox"/> Other: CAPUS </div> </div>				
AGENCY	<div style="display: flex; justify-content: space-between;"> <div> Site Type <div style="border: 1px solid black; padding: 2px; display: inline-block;"> F 0 6 . 0 5 <small>(See codes on reverse)</small> </div> </div> <div> Unique Agency ID Number <div style="border: 1px solid black; width: 100px; height: 20px;"></div> </div> <div> Site Zip Code <div style="border: 1px solid black; width: 100px; height: 20px;"></div> </div> </div>			
CLIENT	<div style="display: flex; justify-content: space-between;"> <div> Year of Birth <small>(YYYY)</small> <div style="border: 1px solid black; width: 60px; height: 20px;"></div> </div> <div> State <div style="border: 1px solid black; width: 40px; height: 20px;"></div> </div> <div> Zip Code <div style="border: 1px solid black; width: 60px; height: 20px;"></div> </div> <div> Client County <div style="border: 1px solid black; width: 100px; height: 20px;"></div> </div> </div>			
TEST 1				
REFERRAL TO CONFIRMATORY TESTING				
900 TEST INFORMATION	Sample Date (MMDDYYYY) <div style="border: 1px solid black; width: 100px; height: 20px;"></div>		Test Election <input checked="" type="checkbox"/> Tested confidentially	If positive result, referral? <input type="checkbox"/> Referred to Community Based Organization (CBO) <input type="checkbox"/> Referred to Local Health Department (LHD) <input type="checkbox"/> Client Declined Referral Name of CBO/LHD: _____
	Worker ID <div style="border: 1px solid black; width: 100px; height: 20px;"></div>			
	Test Technology <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Conventional <input checked="" type="checkbox"/> Fingertick Rapid <input type="checkbox"/> Cleanview <input type="checkbox"/> Oraquick <input type="checkbox"/> NAAT/RNA Testing </div> <div> <input type="checkbox"/> Oral Rapid <input checked="" type="checkbox"/> Other <input type="checkbox"/> Other </div> </div>		Mode of Referral <input type="checkbox"/> Agency representative met client at pharmacy <input type="checkbox"/> Client given referral card	
	Test Result <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate </div> <div> <input type="checkbox"/> Invalid <input type="checkbox"/> No result </div> </div>			
	Result Provided <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes, client obtained result from another agency		If Declined Referral, Why? <input type="checkbox"/> Will see independent physician <input type="checkbox"/> Does not believe test result <input type="checkbox"/> Already knows they are HIV-positive <input type="checkbox"/> Other (describe below)	
	If results not provided, why? <input type="checkbox"/> Declined notification <input type="checkbox"/> Did not return/Could not locate <input type="checkbox"/> Other			
<input checked="" type="checkbox"/> Client was not asked about behavioral risk factors				

Local Use Fields	Notes
<div style="border: 1px solid black; padding: 2px;"> L4 </div>	

Notice: The Virginia Department of Health does not provide HIV test results to immigration agencies.

Aviso: El Departamento de Salud de Virginia no proporciona los resultados de ningún prueba de VIH a agencias de inmigración.

Mail form to: VDH, Division of Disease Prevention, Central Registry Unit, 109 Governor St. Rm 228-E, Richmond, VA 23219

HIV Information and Testing Agreement

Testing provided by Walgreens is voluntary. By signing this form, you agree to take a test that will show if you have antibodies for HIV, the virus that causes AIDS. Antibodies are generated by your immune system every time it comes in contact with a new disease, which means that if you have antibodies for HIV, you are likely HIV-infected. Your body does not immediately develop antibodies, but produces them over the first 90 days of a new infection.

Like a number of other communicable diseases, HIV is a reportable condition in the state of Virginia. This means that if you are diagnosed with HIV, your name and contact information will be reported to the Virginia Department of Health, who will help you get access to medical care. The health department will protect your identity and your records.

People get HIV most often by having unprotected sex or sharing needles/syringes with an infected person. If you get HIV, it can take up to 90 days to develop antibodies. If you may have been exposed to HIV in the past 90 days, it is recommended that you test again in three months regardless of your test result. People who often engage in high-risk behavior should test every three months.

With medical care, most people with HIV stay healthy for years. People who find out early have better health outcomes than people who find out after HIV has damaged their immune systems over a long period of time. People who know they have HIV can also avoid passing the virus to others.

What Kind of Test Will Be Done?

You are receiving a **rapid test**. Rapid tests are simple and accurate when performed at point-of-care by personnel trained to follow manufacturer's instructions. Your pharmacist has been specially trained to conduct your HIV test, and will use a fingerstick lancet to collect a blood specimen. The results of your rapid test will be ready in 1-3 minutes.

What does my Test Result Mean?

If your rapid HIV test is negative, no antibodies for HIV were found. However if you recently (within last 90 days) had unprotected sex or shared needles/syringes, there is a chance that you may be in the "**window period**". This means that you may be infected, but have not yet developed the antibodies that will allow your test to yield an accurate result.

If your rapid test is reactive or preliminary positive, you will need a confirmatory, or follow-up test, to verify the result of the first HIV test. Your testing pharmacist will refer you to a local nonprofit organization or to the local health department for a confirmatory test. The follow up test will be a conventional test, which must be sent to a laboratory. You will need to return within 7-10 days to get your test results.

If your confirmatory test is indeterminate, it may mean that you are still in the process of developing antibodies. It is important that you retest.

Signature: _____

Date: _____

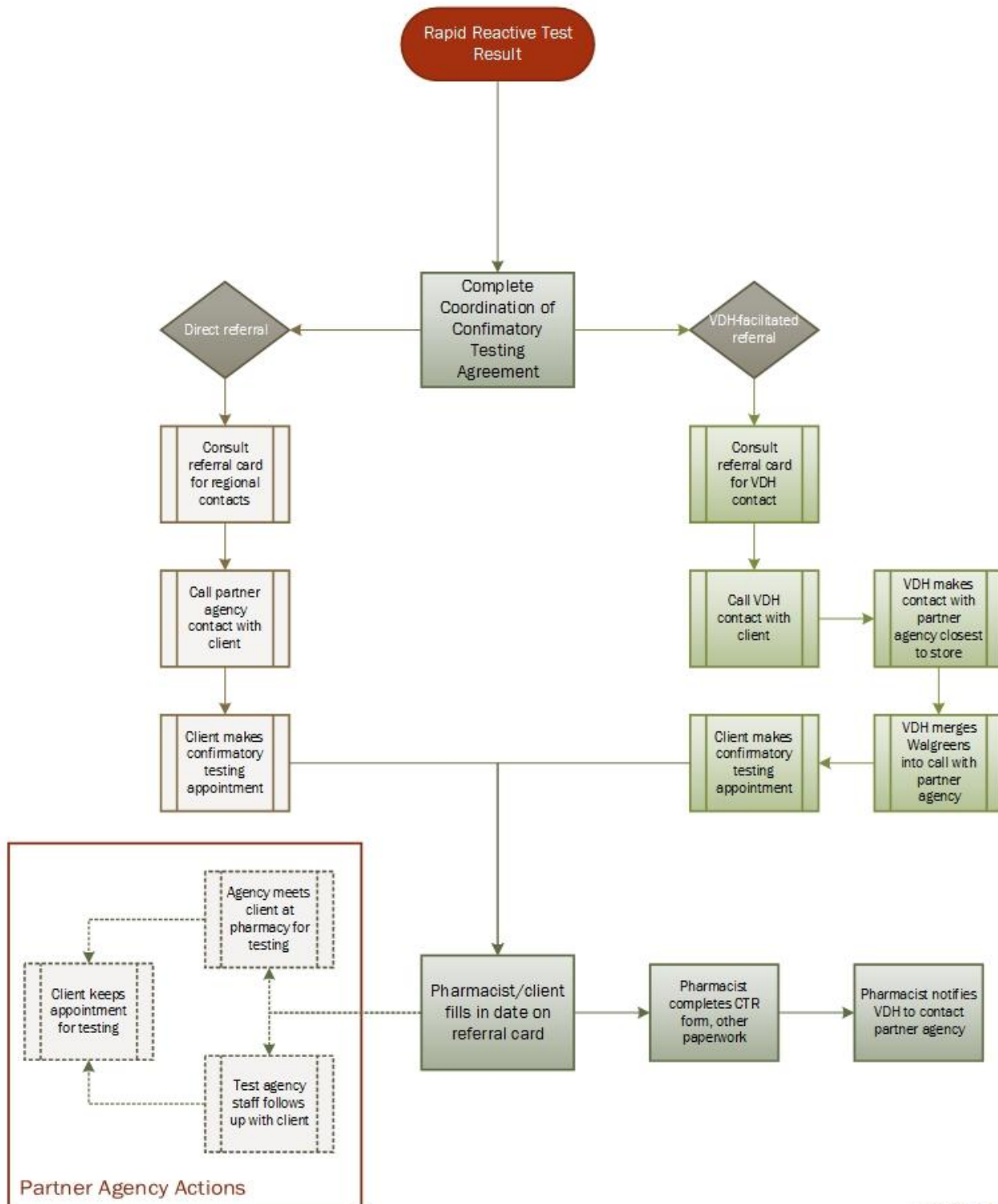
Printed Name: _____

Date of Birth: _____

Attachment C



Pharmacist Referral to Confirmatory Testing



4/11/2014

Attachment D

INSTI HIV-1 Antibody Test Kits and Controls Order Form



ORDER FORM (U.S.)

NOTE: 1. Existing customers (with bioLytical Account No.) will receive an Order Confirmation with the agreed pricing. 2. New or first time customers will be contacted by bioLytical Customer Service in order to set up an account and confirm eligibility.		
Company Name:		Purchase Order No.:
Account No.:	CLIA No.:	Order Placed By:
Phone No.:	Fax No.:	E-mail:

Catalogue and Product Description	Quantity
90-1019 - One INSTI™ HIV-1 Antibody Test with Support Materials	Unit/s
90-1018 - 24 INSTI™ HIV-1 Antibody Tests with Support Materials	Box/es
90-1020 - 24 INSTI™ HIV-1 Antibody Tests without Support Materials	Box/es
80-1071 - INSTI™ HIV-1 Test Controls (Positive and Negative, 80 tests each)	Box/es

Shipping Address:	Billing Address:
-------------------	------------------

Additional Requirements
Required Delivery Date: (Actual delivery date to be confirmed by bioLytical)
Special Shipping Instructions:

Documents to Accompany Shipment: (Check all that apply)	
Certificate of Analysis	MSDS
Certificate of Origin	Other (Please specify)

Labelling and Packaging Requirements:	
Standard Current Catalogue	Other (Please specify)

Special Billing Instructions:

WARNING: The sale, distribution and use of the INSTI™ HIV-1 Antibody Test are restricted. By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the following restrictions on the sale, distribution, and use of the device:	
1. Sale of the INSTI™ HIV-1 Antibody Test is restricted to clinical laboratories <ul style="list-style-type: none"> • That have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met, and • Where there is assurance that operators will receive and use the instructional materials. 	
2. The INSTI™ HIV-1 Antibody Test is approved for use only by an agent of a clinical laboratory.	
3. Test subjects must receive the "Subject Information Brochure" and pre-test counselling prior to specimen collection, and appropriate counselling when test results are provided.	
4. The INSTI™ HIV-1 Antibody Test is not approved for use to screen blood or tissue donors.	

bioLytical Use Only	
Order Entered By: _____ QSP Form 72-01-05, Rev.A	Approved By: _____ <div style="text-align: center; margin-top: 10px;">QA/QC Authorized Signer</div> <div style="text-align: center; margin-top: 10px;">Manufacturing Authorized Signer</div>

Attachment E

Order Form for CTR Forms and INSTI Related Supplies

Order Date	
Store Number	
Contact/Ship to (Full Name. No Initials.)	
Pharmacy Address	
Street 1 (No Post Office Box)	
Street 2 (No Post Office Box)	
City	
State and Zip	
Pharmacy Phone	

Item	Size	Quantity	Type	Urgent (Yes/No)
Counseling, Testing and Referral (CTR) Form – Part 1 ★			Required – Every HIV Test	
Sharps Container with prepaid postage for mail back for disposal and proof of treatment	2 gallon		Container	
Tyvek Envelopes with UPS Mailing Labels				
Underpads	23" x 24"		Package (25)	

★ As the time required to ship forms may vary, it is recommended to keep at least 200 CTR forms on-hand.

FAX ORDER REQUEST TO ATTENTION: The CAPUS Coordinator at 804-864-7970

Attachment F

Walgreens

CLIA# (Enter agency #)

INSTI Rapid HIV Test Problem Documentation

Date	Initials	Lot #	Expiration Date	Problem	Corrective Action Taken

Attachment G

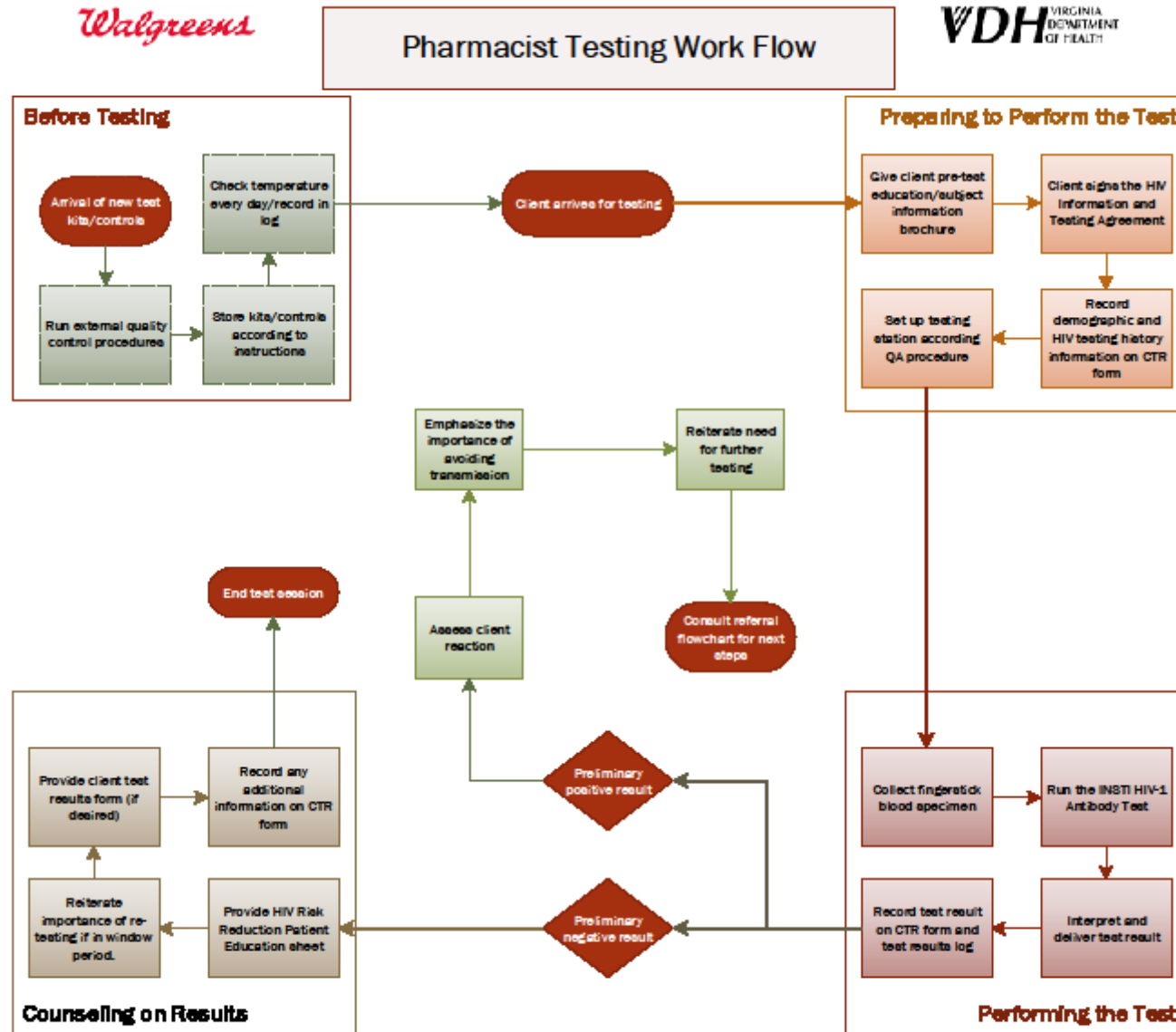
Walgreens

CLIA# (Enter agency #)

INSTI Rapid HIV Test Results Log

CTR Form Barcode	Test Date	Lot #	Test Start Time	Test Read Time	Test Result N = Non-Reactive R = Reactive I = Invalid	Initials of Person Who Performed Test

Attachment H



Attachment I

Coordination of Confirmatory Testing Agreement Form

Instructions

Purpose of Form:

The purpose of this form is to allow the client and the Walgreens site that provides HIV testing to identify and select available community resources. The goals are to help coordinate referral services, assist with closing the referral loop, and allow for easier linkages to care.

Each testing site that initiates this form becomes the owner of this form and their testing site's name should be placed at the top of the page. Each testing site needs to decide if this form will replace or supplement their current consent for services and or release of information form(s). Each agency will also need to decide how and where they want to store and maintain this form.

The instructions on this page will help with the completion of the Coordination of Confirmatory Testing Form.

Please remember, if the form is not complete and accurate, this may cause a delay in obtaining additional services for your client.

Please print clearly using blue or black ink.

Number of Pages: Form 2; Instructions 2

Instructions: Page 1

1. The Walgreens pharmacist or the client needs to print the client's full name, address and date of birth on the top portion of the form.
- 2a. The Walgreens pharmacist will check off the appropriate confidential information to be exchanged.
- 2b. The Walgreens pharmacist will indicate any other information not listed by manually writing in the information.
3. The Walgreens pharmacist will mark which services are requested by exchanging information.
4. The client will need to advise agency representatives of the best contact method(s) and if it is appropriate to leave a message on the phone or at work.
5. The client will also indicate if they would allow sharing of additional information received after the authorization is signed.
6. The Walgreens pharmacist will write in the authorization effective date and advise the client that the authorization date is valid for 24 months from the signature date.
If revoked, the **client must sign and date**. The client is responsible for contacting the agencies to withdraw from their services.
7. The client will sign and date the form acknowledging the purpose of the form.
8. The Walgreens pharmacist will complete their name, address and phone number.

Instructions: Page 2

The agency representative will complete page 2 of the enrollment form and fax to the appropriate agency for referral. **Please be sure to use a fax cover sheet.**

1. The pharmacist referring the client offsite for confirmatory testing using this form will print the client's full name and date of birth.
- 2a. The pharmacist will fax the CCTA to the appropriate referral partner.
- 2b. The pharmacist using this form for referral will write in his/her name.
- 2c. The pharmacist will write in their telephone number and **secure** fax number.
3. When linkage to confirmatory testing has been accomplished, the Patient Navigator, DIS, Testing Counselor, the authorization target, writing Agency name that is receiving the referral for follow up testing.
4. Once attendance to a testing site is confirmed, Linkage Personnel completes date of attendance and circle how referring agency was notified of attended appointment. If sending confirmation by fax, **please be sure to use a fax cover sheet.**

Please note: If you copy these forms to place in a paper chart and are saving paper by copying front to back, please copy Page 2 **UPSIDE DOWN** so it is easier to read while still in the chart.

COORDINATION OF CONFIRMATORY TESTING AGREEMENT
PAGE 1 OF 2

I understand that each agency must have specific information to provide services and benefits. By signing this form, I allow agencies to share certain information about me, for the purpose of coordinating my follow up testing. I further understand that only information relevant to the coordination of my follow up testing will be shared among pertinent staff.

1) I, _____ am signing this form for the opportunity to receive coordination of services.
(Print Client's Full Name)

Client's address _____ Client's Date of Birth _____

2a) I allow the following confidential information about me to be shared:

☐ Contact information ☐ Demographics ☐ Client's testing information

2b) Other information (write-in): _____

3a) I consent that the consented information indicated in item 2a can be released for the following referral arrangements:

☐ Confirmatory HIV testing

4) I may be contacted by the following methods (please check all that apply):

☐ In person only, at this location: _____

☐ Home Phone: _____ May we leave a message? _____

☐ Cell Phone: _____ May we leave a message/text message? _____

☐ Work Phone: _____ May we leave a message? _____

☐ Email: _____ ☐ Letter: _____

5) I allow sharing additional information received after this authorization is signed: ☐ Yes ☐ No

6) This agreement is effective: _____ 6a) If revoked, check box, sign and date ☐ _____
(Date) (Sign and Date)

It is understood that this agreement for the coordination of my care services is valid for 24 months from the agreement date.

In addition, it is understood that in order to assist in the referral process, a health system navigator (HSN), or patient navigator (PN), or other type of linkage to care staff or personnel can attempt to contact me by the above-approved methods, in the event that I miss a scheduled appointment related to my confirmatory HIV testing.

I can withdraw this agreement at any time by informing all referred agencies. The listed agencies must stop sharing information after I inform them that my authorization has been withdrawn. I have the right to know what information about me has been shared, why, when, and with whom it was shared. If I ask, each agency will show me this information. I want all agencies to accept a copy of this form as valid consent to share information. If I do not sign this form, information will not be shared and I will have to contact each agency individually to give information about me that is needed. However, I understand that treatment and services cannot be conditioned upon whether I sign this agreement.

7) Signature(s): _____ Date: _____
(Client or Authorized Person)

8) Person Explaining Form: _____
(Name) (Agency) (Phone Number)

Please fax this sheet to confirmatory testing site.

COORDINATION OF CONFIRMATORY TESTING AGREEMENT
PAGE 2 of 2

1) Client: _____ DOB: _____
(Print)

FOR PATIENT NAVIGATOR, DIS, OR TEST COUNSELOR ONLY

PLEASE COMPLETE AND FAX BACK TO REFERRING PARTY

Please be sure to use a fax cover sheet.

2a) Patient Navigator, DIS, Testing Counselor, or other referral personnel's name: _____

2b) Patient Navigator, DIS, Testing Counselor, or other referral personnel: _____

3) Client was referred to:

Name of CBO, Health Department, or Testing Agency referred to: _____

Date of referral: _____

Date of appointment: _____

Confirmed attendance of appointment (Date verified): _____ Confirmation method (circle one): Phone or Fax

Other type of Service Referral: _____

Agency: _____

Date of referral: _____

Date of appointment: _____

Other type of Service Referral: _____

Agency: _____

Date of referral: _____

Date of appointment: _____

Follow-up Notes:

Please fax this sheet to confirmatory testing agency.

Attachment J

Referral Resources by Region

Eastern Region Referral Contacts

- ☐ **ACCESS AIDS Care** - 222 W. 21st St, Norfolk VA 23517
 - Irma Hinkle - (757) 640-0929 x216, ihinkle@accessaids.org
 - LaDell Adams - (757) 625-6992 x323, ladams@accessaids.org
- ☐ **Norfolk City Health Department**
 - Rosalind Johnson - (757) 683-2768, rosalind.johnson@vdh.virginia.gov
 - Donna Pledger - (757) 683-2804, donna.pledger@vdh.virginia.gov
- ☐ **Peninsula Health District (Newport News)**
 - Brenda Hill, RN - (757) 594-7549, brenda.hill@vdh.virginia.gov
 - Shareef Malik - (757) 594-7337, shareef.malik@vdh.virginia.gov
- ☐ **Hampton Health Department**
 - Gwen Hudgins - (757) 727-1172 x53769 or (757) 315-3769, gwen.hudgins@vdh.virginia.gov
- ☐ **Western Tidewater Health District (Suffolk)**
 - Keith Grant - (757) 594-7542, keith.grant@vdh.virginia.gov
 - Cathy Belcher - (757) 653-3040, cathy.belcher@vdh.virginia.gov
- ☐ **Virginia Beach Health Department**
 - Brian Williams - (757) 518-2667, brian.williams@vdh.virginia.gov
 - Jan Turner - (757) 518-2670, janet.turner@vdh.virginia.gov
- ☐ **Portsmouth Health Department**
 - LaNisha Childs - (757) 393-8585 x8713 or (757) 618-9332, lanisha.childs@vdh.virginia.gov
 - Karla Shuler - (757) 393-8585 x8710, karla.shuler@vdh.virginia.gov

Central Region Referral Contacts

- ☐ **Fan Free Clinic** - 1010 N. Thompson Street, Richmond, VA 23230
 - Cristina Kincaid - (804) 358-6343 x102, ckincaid@fanfreeclinic.org
 - Susan Tellier - (804) 358-6343 x140, stellier@fanfreeclinic.org
- ☐ **Minority Health Consortium** - 208 E. Clay Street, Suite B, Richmond, Virginia 23219
 - Juan Pierce - (804) 225-0820, Juan.Pierce@verizon.net
 - Taheara Jackson - (804) 225-0820, taheara@mhcprevents.org
- ☐ **Chesterfield Health Department**
 - Chris Sydnor - (804) 751-4365, chris.sydnor@vdh.virginia.gov
 - Melissa Williams - (804) 751-4472, melissa.williams@vdh.virginia.gov
- ☐ **Crater Health District (Petersburg)**

- Jean Morrison - (804) 862-8938, jean.morrison@vdh.virginia.gov
- Sterling Stewart - (804) 862-8927, sterling.stewart@vdh.virginia.gov
- ❑ **Crater Health District (Hopewell)**
 - Jean Morrison - (804) 862-8938, jean.morrison@vdh.virginia.gov
 - Sterling Stewart - (804) 862-8927, sterling.stewart@vdh.virginia.gov
- ❑ **Southside Health District (Halifax)**
 - Mimi Nowlin - (434) 947-2866 or (434) 907-3814, yvonne.nowlin@vdh.virginia.gov
 - Lori Ammons - (434) 476-4863 x132, lori.ammons@vdh.virginia.gov
- ❑ **Henrico County Health Department**
 - Margie Benko - (804) 652-3190 x3179, marjorie.benko@vdh.virginia.gov
 - Jenny Calhoun, RN - (804) 652-3190 x3178, jenny.calhoun@vdh.virginia.gov
- ❑ **Richmond City Health Department**
 - Suzanne Roberts - (804) 482-8007 or (804) 381-2616, suzanne.roberts@vdh.virginia.gov

Northern Region Referral Contacts

- ❑ **NoVA Salud, Inc. - 2946 Sleepy Hollow Rd, Suite 3C, Falls Church, VA 22044**
 - Hugo Delgado - (703) 789-4467, hdelgado@novasaludinc.org
 - Ignacio Aguirre - (703) 380-6835, iaguirre@novasaludinc.org
 - Ellin Kao - (703) 776-0378, ekao@novasaludinc.org
 - Rod McCoy - (703) 776-0839, rmccoy@novasaludinc.org
- ❑ **Alexandria City Health Department**
 - Debby Dimon - (703) 746-4936, debby.dimon@vdh.virginia.gov
 - Felisa Batista - (703) 746-7931, felisa.batista@vdh.virginia.gov
- ❑ **Arlington Health Department**
 - Sharron Martin - (703) 228-1239, smartin@arlingtonva.us
 - Lilibeth Grandas - (703) 228-1211, lgrandas@arlingtonva.us
- ❑ **Fairfax County Health Department**
 - Mike Bumbrey - (703) 704-6129 or (202) 285-6427, gerald.bumbrey@fairfaxcounty.gov
 - Carol Wood - (703) 246-8671 or (703) 819-7472, carol.wood@fairfaxcounty.gov
 - Karen Horn - (703) 246-2477, karen.horn@fairfaxcounty.gov
- ❑ **Loudoun County Health Department**
 - Rosalyn Cousar - (703) 777-0236, rosalyn.cousar@loudoun.gov
 - Sheila Reffner - (703) 737-8725, sheila.reffner@loudoun.gov
- ❑ **Prince William Health District (Manassas/Woodbridge)**
 - Megan McHugh - (703) 792-6332 or (571) 238-1312, megan.mchugh@vdh.virginia.gov
 - Judy Flagge - (703) 792-7325, judith.flagge@vdh.virginia.gov

Northwest Region Referral Contacts

- ❑ **AIDS Resource Effort (ARE)** - 333 West Cork St, Winchester, VA 22601
 - Janet Tinkham - (540) 536-5293, jtinkham@valleyhealthlink.com
- ❑ **FAHASS** - 415 Elm St, Fredericksburg, VA 22401
 - Donna Powell - (540) 940-9848, donna@fahass.org
 - Kemisha Denny - (540) 371-7532, kemisha@fahass.org
- ❑ **Thomas Jefferson Health District (Charlottesville)**
 - Elishiba Pradhan - (434) 972-6262, elishiba.pradhan@vdh.virginia.gov
 - Jason Elliott - (434) 972-6278, jason.elliott@vdh.virginia.gov
- ❑ **Thomas Jefferson Health District (Louisa)**
 - Sheri Southall - (540) 967-3703, sheri.southall@vdh.virginia.gov
 - Barbara Knight - (540) 967-3703, barbara.knight@vdh.virginia.gov
- ❑ **Rappahannock-Rapidan Health District (Culpeper)**
 - JoAnne Russell - (540) 829-7350, joanne.russell@vdh.virginia.gov
 - Loraine Dentel - (540) 316-6323, loraine.dentel@vdh.virginia.gov
- ❑ **Rappahannock Health District (Fredericksburg)**
 - Renee Edwards - (540) 322-5942 x5942 or (540) 409-7668, renee.edwards@vdh.virginia.gov
 - Marguerite Bartlett - (540) 899-4142, marguerite.bartlett@vdh.virginia.gov
- ❑ **Lord Fairfax Health District (Winchester)**
 - April Jenkins - (540) 722-3470 x107, april.jenkins@vdh.virginia.gov
 - Leea Shirley - (540) 722-3470, leea.shirley@vdh.virginia.gov
 - Rhona Collins - (540) 722-3470 x128 or (540) 687-1751, rhona.collins@vdh.virginia.gov
- ❑ **Central Shenandoah Health Department (Harrisonburg)**
 - Kim Whetzel - (540) 574-5101 or (540) 574-5241, kim.whetzel@vdh.virginia.gov
 - Senta Lanier - (540) 574-5100, senta.lanier@vdh.virginia.gov

Central Region Referral Contacts

- ❑ **The Drop-In Center** - 356 Campbell Ave SW, Roanoke, VA 24016
 - Pamela Meador - (540) 952-2437 or (540) 815-4665, pamm@councilofcommunityservices.org
- ❑ **Roanoke City Health Department**
 - Rick Wiseley - (540) 204-9979, earl.wiseley@vdh.virginia.gov
 - Cynthia Perkins - (540) 204-9694, cynthia.perkins@vdh.virginia.gov
- ❑ **West Piedmont Health District (Martinsville)**
 - Pam Rorrer - (276) 638-2311 x115, pamela,rorrer@vdh.virginia.gov
 - Careen Rodgers - (276) 638-2311 x114, careen.rodgers@vdh.virginia.gov

- ❑ **Pittsylvania-Danville Health District (Danville)**
 - Dave Emerson - (434) 766-9814, david.emerson@vdh.virginia.gov
- ❑ **Central Virginia Health District (Lynchburg)**
 - Mimi Nowlin - (434) 947-2866 or (434) 907-3814, yvonne.nowlin@vdh.virginia.gov
 - Ruby Jones - (434) 947-6712, ruby.jones@vdh.virginia.gov
- ❑ **Southside Health District (Halifax)**
 - Mimi Nowlin - (434) 947-2866 or (434) 907-3814, yvonne.nowlin@vdh.virginia.gov
 - Lori Ammons - (434) 476-4863 x132, lori.ammons@vdh.virginia.gov
- ❑ **New River Health District (Christiansburg)**
 - Hedy Ruohoneiemi - (540) 585-3345, hedy.ruohoneiemi@vdh.virginia.gov
 - Aimee Dickenson - (540) 440-2154 or (276) 880-4519, aimee.dickenson@vdh.virginia.gov
 - Reba Hite - (540) 585-3353, reba.hite@vdh.virginia.gov

Attachment K

Sample Confirmatory Testing Referral Card (CTRC)

Front Side

Pharmacist _____ Contact: _____ Appt. Date _____ Time: _____

Site info _____ Additional Information: _____

Contact _____

Virginia Department of Health Referral Contacts

☐ **VDH Referral Phone** - CAPUS Coordinator 804-397-5056. This phone is monitored 24 hours a day, 7 days a week by VDH staff. In the event that you reach a recording, please leave your name, and the best way (and time) to reach you. The voicemail box is confidential.

☐ **VDH Resource Hotline** - 1-800-533-4148

Eastern Virginia Community Based Organizations

- ☐ **ACCESS AIDS Care** - 222 W. 21st St, Norfolk VA 23517
 - ☐ Irma Hinkle - (757) 640-0929 x216, ihinkle@accessaids.org
 - ☐ LaDell Adams - (757) 625-6992 x323, ladams@accessaids.org

See reverse for Local Health Department Contacts

Reverse Side

Eastern Region Local Health Departments

- ☐ **Norfolk City Health Department**
 - ☐ Rosalind Johnson - (757) 683-2768, rosalind.johnson@vdh.virginia.gov
 - ☐ Donna Pledger - (757) 683-2804, donna.pledger@vdh.virginia.gov
- ☐ **Peninsula Health District (Newport News)**
 - ☐ Brenda Hill, RN - (757) 594-7549, brenda.hill@vdh.virginia.gov
 - ☐ Shareef Malik - (757) 594-7337, shareef.malik@vdh.virginia.gov
- ☐ **Hampton Health Department**
 - ☐ Gwen Hudgins - (757) 727-1172 x53769 or (757) 315-3769, gwen.hudgins@vdh.virginia.gov
- ☐ **Western Tidewater Health District (Suffolk)**
 - ☐ Keith Grant - (757) 594-7542, keith.grant@vdh.virginia.gov
 - ☐ Cathy Belcher - (757) 653-3040, cathy.belcher@vdh.virginia.gov
- ☐ **Virginia Beach Health Department**
 - ☐ Brian Williams - (757) 518-2667, brian.williams@vdh.virginia.gov
 - ☐ Jan Turner - (757) 518-2670, janet.turner@vdh.virginia.gov
- ☐ **Portsmouth Health Department**
 - ☐ LaNisha Childs - (757) 393-8585 x8713 or (757) 618-9332, lanisha.childs@vdh.virginia.gov
 - ☐ Karla Shuler - (757) 393-8585 x8710, karla.shuler@vdh.virginia.gov

Attachment L

Virginia Department of Health Policy Regarding the Provision of Service to Minors

Pediatric HIV Testing Policies & Procedures

Rapid test kits currently approved by the FDA only function when used with specimens from individuals over 13 years of age. If a family or guardian presents with an HIV testing need for a child under thirteen, they should not be referred to a community partner using the provided resource sheet. Instead, the following steps should be taken:

1. The pharmacy should call VDH staff to work through the case:

Heather Bronson, (804)-864-8020 (primary contact)

Elaine Martin, (804)-864-7962 (secondary contact)

Diana Jordan, (804)-864-7955 (tertiary contact)

Please have available as much information as possible:

- Age of the child
 - Reason child needs testing (perinatal versus sexual transmission)
 - If perinatal transmission is suspected:
 - Is the mother newly diagnosed or previously positive?
 - Is the mother in care and does she have a case manager?
 - Where is she in care?
2. If the mother is positive and is not in care, an active referral should be made. A release should be obtained to share the child's information with the case manager.
 3. If the child has a pediatrician and is otherwise healthy, a release should be obtained to provide the mother's HIV status to the physician. The physician should perform screening for HIV symptoms and a HIV serology (with viral detection method at the clinician's discretion). *If the mother refuses to sign a release, please contact VDH for further instructions.*
 4. If the child does not have a pediatrician, a release should be obtained to provide the mother's HIV status to a Pediatric Infectious Disease (ID) Specialist (see information below) with the child referred for an evaluation. *If the mother refuses to sign a release, please contact VDH for further instructions.*

Points to consider when coordinating testing for a child under 13

Virologic assays that directly detect HIV must be used to diagnose HIV infection in infants younger than 18 months; antibody tests should not be used.

Diagnosis of HIV-1 infection in children with non-perinatal exposure or children with perinatal exposure aged >24 months relies primarily on HIV antibody tests.¹ FDA-approved diagnostic tests include:

- Antigen/antibody combination immunoassays (fourth-generation tests) that detect HIV-1/2 antibodies as well as HIV-1 p24 antigen: Recommended for initial testing.
- HIV-1/2 immunoassays (third-generation antibody tests): Alternative for initial testing.
- HIV-1/HIV-2 antibody differentiation immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies (Multispot HIV-1/HIV-2 test): Recommended for supplemental testing.

- HIV-1 Western blot and HIV-1 indirect IFAs (first-generation tests): Alternative for supplemental testing.
- HIV-1 NAT (HIV qualitative RNA assay)

If acute HIV infection or end-stage AIDS is suspected, virologic testing may be necessary to diagnose HIV infection because HIV-1/2 antibody immunoassays, HIV-1 Western blot, or HIV-1 IFA may be negative in these situations.

Please refer to the linked documents below for a full package insert.

bioLytical INSTI Rapid HIV-1 Antibody Test: Customer Letter

[http://www.biolyticalus.com/insti_documents/50-1109%20\(Artwork%20B\)%20Customer%20Letter%20\(US\).pdf](http://www.biolyticalus.com/insti_documents/50-1109%20(Artwork%20B)%20Customer%20Letter%20(US).pdf)

bioLytical INSTI Rapid HIV-1 Antibody Test: Package Insert

[http://www.biolyticalus.com/insti_documents/50-1080%20\(Artwork%20C\)%20Package%20Insert%20\(US\).pdf](http://www.biolyticalus.com/insti_documents/50-1080%20(Artwork%20C)%20Package%20Insert%20(US).pdf)

bioLytical INSTI Rapid HIV-1 Antibody Test: Subject Information Brochure

[http://www.biolyticalus.com/insti_documents/50-1108%20\(B\)%20US%20Subject%20Information%20Brochure.pdf](http://www.biolyticalus.com/insti_documents/50-1108%20(B)%20US%20Subject%20Information%20Brochure.pdf)

bioLytical INSTI Rapid HIV-1 Antibody Test: Summary of Safety and Effectiveness Data

[http://www.biolyticalus.com/insti_documents/50-1110%20\(B\)%20Summary%20of%20Safety%20and%20Effectiveness%20\(FDA\).pdf](http://www.biolyticalus.com/insti_documents/50-1110%20(B)%20Summary%20of%20Safety%20and%20Effectiveness%20(FDA).pdf)

bioLytical INSTI Rapid HIV-1 Antibody Test: Quick Reference Guide

[http://www.biolyticalus.com/insti_documents/50-1125%20\(C\)%20Quick%20Reference%20Guide%20\(US\).pdf](http://www.biolyticalus.com/insti_documents/50-1125%20(C)%20Quick%20Reference%20Guide%20(US).pdf)

Attachment M

Regional Pediatric Testing Resources

Eastern

Children's Hospital of the King's Daughters
601 Children's Lane
Norfolk, VA 23507
Phone: (757) 668-7238
Infectious Diseases (CSG) Physicians
Kenji Cunnion, MD
Randall Fisher, MD
Laura Sass, MD

Central

Virginia Commonwealth University,
Infectious Disease Clinic: Pediatrics
1001 E. Marshall Street
Richmond, VA 23219
(804) 828-4568
Suzanne Lavoie, MD
David Friedel, MD
Beth Marshall, MD

Northwest

University of Virginia Children's Hospital,
Infectious Disease Clinic: Pediatrics
Primary Care Center, 4th Floor
1215 Lee St., Charlottesville, VA 22908
(434) 982-1700
Greg Townsend, MD

Northern

Children's National Medical Center
111 Michigan Ave
Washington, D.C. 20010
(202) 476-6131
Steve Zeichner, MD

Southwest

Carilion Infectious Disease Clinic
1906 Bellview Ave.
Roanoke, VA 24014
(540) 981-7715
Thomas Kerkerling, MD
Charles Schleupner, MD

Attachment N

Walgreens Store Site IDs

Site ID	Site Name	Site Address	Site City	State	Zip	Phone
5001	Walgreens - #10616	6717 Richmond Hwy.	Alexandria	VA	22306	703-721-0912
5002	Walgreens - #11234	10671 Sudley Manor Dr.	Manassas	VA	20109	703-257-2894
5003	Walgreens - #13156	8697 Sudley Rd.	Manassas	VA	20110	703-331-3716
5004	Walgreens - #15133	1860 Town Center Dr., Suite G-200	Reston	VA	20190	703-736-2824
5005	Walgreens - #12017	3590 Virginia Ave.	Collinsville	VA	24078	276-647-1101
5006	Walgreens - #15112	1500 Piney Forest Rd.	Danville	VA	24540	434-836-7144
5007	Walgreens - #1257	103 Commonwealth Blvd.	Martinsville	VA	24112	276-632-6457
5008	Walgreens - #11773	3220 Halifax Rd.	South Boston	VA	24592	434-575-5338
5009	Walgreens - #12360	3901 Oaklawn Blvd.	Hopewell	VA	23860	804-452-2542
5010	Walgreens - #9779	4845 S. Laburnum Ave.	Richmond	VA	23231	804-226-4581
5011	Walgreens - #11571	5650 Plank Rd.	Fredericksburg	VA	22407	540-786-5883
5012	Walgreens - #4924	2232 E. Little Creek Rd.	Norfolk	VA	23518	757-480-4116
5013	Walgreens - #9975	1309 Richmond Rd.	Williamsburg	VA	23185	757-229-0962
5014	Walgreens - #9949	42025 Village Center Plaza	Aldie	VA	20105	703-722-2829
5015	Walgreens - #10233	7629 Richmond Hwy.	Alexandria	VA	22306	703-768-5901
5016	Walgreens - #10331	13926 Lee Highway	Centreville	VA	20120	703-259-6200
5017	Walgreens - #9417	3489 Seminole Trail	Charlottesville	VA	22911	434-964-1082
5018	Walgreens - #13126	10230 Iron Bridge Rd.	Chesterfield	VA	23832	804-748-5010
5019	Walgreens - #11675	15250 Montanus Dr.	Culpepper	VA	22701	540-727-8976
5020	Walgreens - #10712	10320 Main St.	Fairfax	VA	22030	703-591-1025
5021	Walgreens - #11572	500 Settlers Landing Rd.	Hampton	VA	23669	757-723-7614
5022	Walgreens - #10923	412 E Main St.	Louisa	VA	23093	540-967-0771
5023	Walgreens - #10691	5006 Boonsboro Rd.	Lynchburg	VA	24503	434-386-6412
5024	Walgreens - #10140	14400 Warwick Blvd.	Newport News	VA	23608	757-874-5084
5025	Walgreens - #10713	26108 Cox Rd.	Petersburg	VA	23803	804-863-4922
5027	Walgreens - #10106	3520 Ellwood Ave.	Richmond	VA	23221	804-342-8864
5028	Walgreens - #7605	2351 Franklin Rd., S.W.	Roanoke	VA	24014	540-985-6491
5029	Walgreens - #12800	8414 Old Keene Mill Rd, Unit A	Springfield	VA	22152	703-913-6712
5030	Walgreens - #10332	3633 Bridge Rd.	Suffolk	VA	23435	757-686-4793
5031	Walgreens - #12032	3364 Princess Anne Rd. #501	Virginia Beach	VA	23456	757-468-5879
5032	Walgreens - #11573	645 E. Jubal Early Dr.	Winchester	VA	22601	540-667-1282
5033	Walgreens - #13790	14095 Jefferson Davis Hwy.	Woodbridge	VA	22191	703-491-3630

Attachment O

Walgreens HIV Testing Sites & Closest Local Health Departments

Site ID	Site Name	Address	City	State	Zip	Closest Local Health Department	Phone	Distance (mi)
5001	Walgreens - #10616	6717 Richmond Hwy.	Alexandria	VA	22306	Mt. Vernon/Fairfax HD,8350 Richmond Hwy, Alexandria, VA 22309	703.704.5203	3.4
5002	Walgreens - #11234	10671 Sudley Manor Dr.	Manassas	VA	20109	Prince William HD,9301 Lee Avenue,Manassas VA 20110	703.792.6300	4.0
5003	Walgreens - #13156	8693 Sudley Rd.	Manassas	VA	20110	Prince William HD,9301 Lee Avenue,Manassas VA 20110	703.792.6300	1.4
5004	Walgreens - #15133	1860 Town Center Dr., # G-2	Reston	VA	20190	Herndon/Reston HD,1850 Cameron Glen Dr, Reston VA 20190	703.481.4242	0.5
5005	Walgreens - #12017	3590 Virginia Ave.	Collinsville	VA	24078	Martinsville HD,295 Commonwealth Blvd W,Martinsville VA 24112	276.638.2311	3.5
5006	Walgreens - #15112	1500 Piney Forest Rd.	Danville	VA	24540	Danville HD,326 Taylor Dr, Danville VA 24541	434.799.5190	6.6
5007	Walgreens - #1257	103 Commonwealth Blvd.	Martinsville	VA	24112	Martinsville HD,295 Commonwealth Blvd,Martinsville VA 24112	276.638.2311	1.0
5008	Walgreens - #11773	3220 Halifax Rd.	South Boston	VA	24592	Halifax HD,1030 Cowford Rd,Halifax VA 24558	434.476.4863	2.9
5009	Walgreens - #12360	3901 Oaklawn Blvd.	Hopewell	VA	23860	Hopewell HD,220 Appomattox St,Hopewell VA 23860	804.458.1297	4.0
5010	Walgreens - #9779	4845 S. Laburnum Ave.	Richmond	VA	23231	Henrico HD East Clinic,1400 N. Laburnum Ave,Richmond VA 23223	804.652.3190	2 minutes
5011	Walgreens - #11571	5650 Plank Rd.	Fredericksburg	VA	22407	Fredericksburg HD,608 Jackson Street Fredericksburg VA 22401	540.899.4142	6.4
5012	Walgreens - #4924	2232 E. Little Creek Rd.	Norfolk	VA	23518	Norfolk HD,830 Southampton VA 23510	757.683.2800	8.0
5013	Walgreens - #9975	1309 Richmond Rd.	Williamsburg	VA	23185	Peninsula HD,416 J Clyde Blvd,Newport News VA 23601	757.594.7300	24.3
5014	Walgreens - #9949	42025 Village Center Plaza	Aldie	VA	20105	Herndon/Reston HD,1850 Cameron Glen Dr, Reston VA 20190	703.481.4242	16.7
5015	Walgreens - #10233	7629 Richmond Hwy.	Alexandria	VA	22306	Mt. Vernon/Fairfax HD,8350 Richmond Hwy, Alexandria VA 22309	703.704.5203	1.9
5016	Walgreens - #10331	13926 Lee Highway	Centreville	VA	20120-2415	Fairfax HD,3750 Old Lee Hwy, Fairfax VA 22030	703.246.7100	9.2
5017	Walgreens - #9417	3489 Seminole Trail	Charlottesville	VA	22911	Albemarle/Charlottesville HD,1138 Rose Hill Dr #108, Charlottesville VA 22903	434.972.6200	7.7
5018	Walgreens - #13126	10230 Iron Bridge Rd.	Chesterfield	VA	23832	Chesterfield HD,9501 Lucy Corr Circle,Chesterfield VA 23832	804.748.1691	0.9
5019	Walgreens - #11675	15250 Montanus Dr.	Culpepper	VA	22701-2514	Culpeper County HD,640 Laurel St.,Culpeper VA 22701	540.829.7350	6.8
5020	Walgreens - #10712	10320 Main St.	Fairfax	VA	22030	Fairfax HD,3750 Old Lee Hwy, Fairfax VA 22030	703.246.7100	0.5
5021	Walgreens - #11572	500 Settlers Landing Rd.	Hampton	VA	23669-4031	Hampton HD,1320 LaSalle Avenue,Hampton VA 23669	757.727.1140	1.2
5022	Walgreens - #10923	412 E Main St.	Louisa	VA	23093	Louisa County HD,101 Ashley St.,Louisa VA 23093	540-967-3703	0.7
5023	Walgreens - #10691	5006 Boonsboro Rd.	Lynchburg	VA	24503-1802	Lynchburg HD,1900 Thomson Dr, Lynchburg VA 24501	434.947.6785	5.3
5024	Walgreens - #10140	14400 Warwick Blvd.	Newport News	VA	23608	Peninsula HD,416 J Clyde Morris Blvd.,Newport News VA 23601	757.594.7305	5.8
5025	Walgreens - #10713	26108 Cox Rd.	Petersburg	VA	23803-6566	Petersburg HD,301 Halifax St.,Petersburg VA 23803	804.863.1652	3.2
5027	Walgreens - #10106	3520 Ellwood Ave.	Richmond	VA	23221-2723	Richmond HD,400 E Cary St, Richmond VA 23219	804.205.3500	4.1
5028	Walgreens - #7605	2351 Franklin Rd., S.W.	Roanoke	VA	24014-1111	Roanoke City HD,1502 Williamson Rd NE, Roanoke VA 24012	540.283.5050	3.9
5029	Walgreens - #12800	8414 Old Keene Mill Rd, Unit A	Springfield	VA	22152	Springfield HD,8136 Old Keene Mill Rd.,Springfield VA 22152	703.569.1031	0.4
5030	Walgreens - #10332	3633 Bridge Rd.	Suffolk	VA	23435-1807	Suffolk HD,135 Hall Ave, Suffolk VA 23434	757.514.4700	13.4
5031	Walgreens - #12032	3364 Princess Anne Rd. #501	Virginia Beach	VA	23456-2610	Virginia Beach HD, Pembroke Corporate Center III, 4452 Corporation Lane, Virginia Beach VA 23462	757-518-2700	7.0
5032	Walgreens - #11573	645 E. Jubal Early Dr.	Winchester	VA	22601-5179	Frederick/Winchester HD,10 Baker St, Winchester VA 22601	540.722.3470	1.8
5033	Walgreens - #13790	14095 Jefferson Davis Hwy.	Woodbridge	VA	22191	Prince William County HD,4001 Prince William Pkwy,Woodbridge VA 22192	703.792.7300	5.0

Attachment P

Health District Contact List

Health Districts	Primary Contact	Phone Number	Additional Contact(s)	Phone Number(s)
Alexandria				
Alexandria HD	Debby Dimon	703-746-4936	Felisa Batista	703-746-7931
			Kimberly Ford	703-746-4771
Alleghany				
Botetourt	Sandy McBride	540-473-7211		
Clifton Forge	Teresa Byer	540-962-2173		
Covington HD	Teresa Byer	540-962-2173		
Craig County HD	Pat Johnston	540-864-5136		
Salem/Roanoke County HD	Sheila Wilson	540-387-5530		
Vinton/Roanoke County HD	Paula Shepherd	540-857-7800		
Arlington				
Arlington HD	Sharron Martin	703-228-1239	Lilibeth Grandas	703-228-1211
Chesapeake				
Chesapeake HD	Marquita Hill	757-382-8649	Wanda Santos	757-382-8601
			Julia Adams	757-382-8615
Chesterfield				
Chesterfield County HD	Chris Sydnor	804-751-4365	Melissa Williams	804-751-4472
			Cynthia Hollar	804-748-1648
			Faye Bates	804-751-4634
			Krystal Oliver	804-748-1758
Colonial Heights City HD	Vicki Stamps	804-520-9380		
Powhatan County HD	Jeannine Uzel	804-748-1706		
Chickahominy				
Charles City County HD	Kim Blount	804-829-2490	Grace Jones	804-829-2490
Goochland County HD	Leslie Stone	804-556-6237	Cindy Moss	804-556-6240
Hanover County HD	Gavin Landry	804-365-4328	Lynn Shearin	804-365-4323
New Kent County HD	Aida Zayas	804-966-9640	Nancy Davis	804-966-9640
Crater				
Dinwiddie County HD	Tracy Bishop	804-469-3771 ext 114	Tammy Varney - RN	804-469-3771 ext 110
Emporia/Greensville	Becky Gayle	434-348-4210 ext 228	Erica Ellis	434-348-4210 ext 227
Hopewell City HD	Carol Hundley	804-668-7178		
Petersburg HD	Sterling Stewart	804-863-1652 ext 8927	Jean Morrison	804-862-8938

Health Districts	Primary Contact	Phone Number	Additional Contact(s)	Phone Number(s)
Prince George County HD	Cynthia Hancock	804-733-2630 ext 4306	Joyce Ndubueze	804-733-2630 ext 4305
Surry County HD	Bee Johns - RN	757-294-3185 ext 105		
Sussex County HD	Lori Deprisco	434-246-8611 ext 18		
Central Shenandoah				
Bath County HD	Jackie Baughan	540-839-7246		
Buena Vista City HD	Laura Brown	540-261-2149		
Harrisonburg HD	Senta Lanier	540-574-5100		
Lexington HD	Marcia Tingler Oliver	540-463-3185 ext. 120		
Staunton HD	Judy Barnhardt	540-332-7830 ext. 304		
Waynesboro City HD	Pamela Coleman	540-949-0137 ext. 125		
Central Virginia				
Amherst County HD	Lisa Barber	434-946-9408	Pat Read, Supervisor	434-221-6648 cell
Appomattox HD	Sasha Garrett	434-352-2313	Sabrina Wood	434-352-2313
			Pat Read, Supervisor	434-221-6648 cell
Bedford County HD	Cindy Dolan	540-586-7952	Michelle Warden	540-586-7952
			Pat Read, Supervisor	434-221-6648 cell
Campbell County HD	Becky Parker	434-592-9550	Kenita Emory	434-592-9550
			Pat Read, Supervisor	434-221-6648 cell
Lynchburg City HD	Mimi Nowlin, DIS	434-947-6785	Teresa Miller	434-947-6785
			Gay Reynolds	434-947-6785
			Denise Witt	434-947-6785
			Ruby Jones, Supervisor	434-947-6712
Cumberland Plateau				
Buchanan County HD	Vanessa Roberts	276-244-3117	Hannah Shelton	276-935-4591
Dickenson County HD	Heather Childress	276-926-4979		
Russell County HD	Anna Harris	276-889-7621		
Tazewell County HD	Carol Chambers - RN	276-988-5585		
Eastern Shore				
Accomack County HD	Joni White	757-787-5880	Kathy Lewis	757-787-5880
Northampton County HD	Patrina Keyes	757-442-6228	Donisha Fleming	757-442-6228
Fairfax				
Fairfax County	Mike Bumbrey	703-704-6129	Susan Fey	703-246-8715
	Carol Wood	703-246-2411	Katie Brewer	703-246-8704
	Karen Horn	703-246-2477		
Hampton				
Hampton HD	Gwen Hudgins	757-315-3769		
Henrico				
Henrico County HD	Margie Benko	804-652-3179	Jenny Calhoun	804-652-3178
			Linda Santmier	804-652-3177
Lenowisco				
Lee County HD	April Hughes	276-346-4388		
Scott County HD	Leslie Gillenwater	276-386-8015		

Health Districts	Primary Contact	Phone Number	Additional Contact(s)	Phone Number(s)
Wise/Norton HD	Donna Miller	276-328-1918		
Lord Fairfax				
Clarke County	Mary Borger	540-955-1033	Ann Judge	540-955-1033
Frederick/Winchester	April Jenkins	540-722-3470	Leea Shirley	540-722-3470
			Rhona Collins	540-722-3470
Page County	Tom Minke	540-743-6528	Loretta Wright	540-743-6528
Shenandoah County	Liz Andrews	540-459-3733	Phoebe Bowman	540-457-6961
Warren County	Paula Mills	540-635-3159	Nyree Rappole	540-722-3470
Loudoun				
Loudoun County	Rosalyn Cousar	703-777-0236	Sheila Reffner	703-737-8725
Mount Rogers				
Bland County HD	Cherie Stowers - RN	276-688-3642	Desirae Elkins	276-688-3642
Bristol City HD	Karen Davis - RN	276-642-7335		
Carroll County HD	Mary Ann Hall - RN	276-730-3180		
Galax City HD	Sara Price	276-236-6127	Mount Rogers HD	
Smyth County HD	Julie Earp - RN	276-781-7460	Mount Rogers HD	
Washington County HD	Sheila Jouett - LPN	276-676-5604	Mount Rogers HD	
Grayson County HD	Kim Coleman - RN	276-773-2961	Mount Rogers HD	
Wythe County HD	Rhoda Thomas - RN	276-228-5507	Mount Rogers HD	
New River				
Floyd County HD	Rebekah Kinsley - RN	540-745-5585	New River HD	
Giles County HD	Susan Strong	540-235-3135		
Montgomery County HD	Hedy Ruohoneiemi	540-585-3345	New River HD	
Pulaski County HD	Susan Strong	540-440-2155	Aimee Dickenson	276-880-4519
Radford City HD	Brittani Blevins	540-267-8255		
Norfolk				
Norfolk City HD	Rosalind Johnson	757-683-2768	Donna Pledger	757-683-2804
Peninsula				
Newport News HD	Brenda Hill - RN	757-594-7549	Shareef Malik	757-594-7337
Piedmont				
Amelia County HD	Annette Wetzel	804-561-2711	Cindy DeBusk	434-392-3984
Buckingham County HD	Debbie Snoddy	434-969-4244	Cindy DeBusk	434-392-3984
Cumberland County HD	Rhonda Cox	804-492-4661	Cindy DeBusk	434-392-3984
Lunenburg County HD	Tina Armstrong	434-542-5251	Cindy DeBusk	434-392-3984
Nottoway County HD	Tammie Jackson	434-645-7595	Cindy DeBusk	434-392-3984
Prince Edward County HD	Kim Ball	434-392-8187	Cindy DeBusk	434-392-3984
Charlotte County HD	Kitty Mason	434-542-5251	Cindy DeBusk	434-392-3984

Health Districts	Primary Contact	Phone Number	Additional Contact(s)	Phone Number(s)
Pittsylvania/Danville				
Pittsylvania County HD	Dave Emerson	434-766-9814		
Danville City	Dave Emerson	434-766-9814		
Portsmouth				
Portsmouth City HD	Lanisha Childs	757-393-8585 ext 8713 or 757-618-9332	Karla Shuler	757-393-8585 ext 8710
Prince William				
Prince William HD	Megan McHugh	703-792-6332	Judy Flagge - RN	703-792-7325
Rappahannock				
Caroline County HD	Cassie Draggon-Sheppard	540-633-5465	Jean Johnson	540-659-7176 ext 116
Fredericksburg City	Renee Edwards	540-322-5942	Marguerite Bartlett	540-899-4142
King George County HD	Judy Kulynych	540-709-5134	Michelle Cantrell	540-709-5136
Spotsylvania County HD	Alyce Finch	540-507-7417	Rachelle Snyder	540-507-7416
Stafford County HD	Vera Lloyd	540-659-7176 ext 128	Jean Johnson	540-659-7176 ext 116
Rappahannock/Rapidan				
Culpeper County HD	JoAnne Russell	540-829-7350	Loraine Dentel	540-316-6323
Fauquier County HD	Lori Tarasovich	540-347-6400		
Madison County HD	JoAnne Russell	540-829-7350	Wanda Apperson	540-738-4008
Orange County HD	Terry Hawkins	540-308-6106		
Rappahannock County HD	Karen Flynn - RN	540-675-3516		
Richmond				
Richmond City HD	Suzanne Roberts	804-482-8007		
Roanoke				
Roanoke City HD	Rick Wisely	540-204-9979	Cynthia Perkins	540-204-9694
			Sheila Wilson	540-283-5034
			Pam Rolen	540-204-9709
Southside				
Brunswick County HD	Audrey Holloway	434-848-2525	Deborah Brockwell	434-848-2525 ext 106
Halifax County HD	Lori Ammons	434-476-4863	Sally Settle	434-476-4863
Mecklenburg County HD	Mary Parker	434-738-6545	Julia Gwatney	434-738-6545
Thomas Jefferson				
Albemarle/Charlottesville HD	Jason Elliott	434-972-6278	Elishiba Pradhan	434-972-6262
Fluvanna County HD	Gail 'Dee' Berry	434-972-6262	Paula Aldridge	434-591-1960
Greene County HD	Bella Burnett	434-985-2262	Julia Simpson	434-985-2262
Louisa County HD	Sheri Southall	540-967-3703	Barbara Knight	540-967-3703
Nelson County HD	Joan Richards	434-972-6203		
Three Rivers				
Essex County HD	Celia Collier	804-693-2445 ext 1401	Holly Balderson	804-443-3396

Health Districts	Primary Contact	Phone Number	Additional Contact(s)	Phone Number(s)
Gloucester County HD	Celia Collier	804-693-2445 ext 1401	Lisa Elliott	804-693-2445
King & Queen County HD	Celia Collier	804-693-2445 ext 1401	Margaret Mitchell	804-785-6154
King William County HD	Celia Collier	804-693-2445 ext 1401	Kim Carlton	804-769-4988
Lancaster County HD	Celia Collier	804-693-2445 ext 1401	Lisa Elliott	804-462-5197
Mathews County HD	Celia Collier	804-693-2445 ext 1401	Karri Murphy	804-725-7131
Middlesex County HD	Celia Collier	804-693-2445 ext 1401	Pam Gurley	804-758-2381
Northumberland County HD	Celia Collier	804-693-2445 ext 1401	Amanda Hamlin	804-580-3731
Richmond County HD	Celia Collier	804-693-2445 ext 1401	Margaret Mitchell	804-333-4043
Westmoreland County HD	Celia Collier	804-693-2445 ext 1401	Beverly Thomas	804-493-1124
Virginia Beach				
Virginia Beach City HD	Brian Williams	757-518-2667	Jan Turner	757-518-2670
			Janie Spence	757-518-2688
			Wendy Preisach	757-518-2719
West Piedmont				
Franklin County HD	Lois Hodges	540-484-0292		
Henry/Martinsville HD	Pam Rorrer	276-638-2311 ext 115	Careen Rodgers	276-638-2311 ext 114
Patrick County HD	Sandra Anglin	276-693-2073		
Western Tidewater				
Isle of Wight County HD	Marli Laudun	757-279-3074	Jacqueline Griffin	757-279-3073
Southampton County HD	Keith Grant	757-594-7542	Cathy Belcher	757-653-3040
			Patty Story	757-653-3040
			Mary Walton	757-653-3040
Suffolk City HD	Keith Grant	757-594-7542	Vickie Barnes	757-514-4706
Franklin City HD	Debra Johnson	757-562-6109	Cathy Belcher	757-514-4700
			Teresa Edwards	757-562-6109

Created 02/12/2015

Version 2 02/19/2015

Attachment Q

Verification of Previous Diagnosis Form

Client Information

Client Full Name	Date of Encounter
Client Date of Birth	Client Social Security Number
Sex (At Birth)	Race/Ethnicity
Date of Diagnosis	State Of Diagnosis
Current Address	Date time Phone Number

Notes